

**A CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHADRUGIN  
THE TREATMENT OF KATTUMANTHAM (DYSPEPSIA)**

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## 1. INTRODUCTION

The Siddha system of medicine is one of the ancient systems contemporaneous with those of the submerged lands, Egyptian, Chinese and Grecian medicine. The unique nature of this system is continuous service to humanity for more than 5000 years in combating disease and in maintaining its physical, mental and moral health.

Siddha system was developed by Siddhars. Siddhars are super human being. According to them physical body plays an important role in our life. It becomes our duty to keep it pure and perfect by regulating energy forces existing in every individual, supplying necessary fuel to achieve proper balance, which is health and avoid imbalance which is illness.

The future of human society depends on the ability of children to achieve their optimal physical growth and psychological development. Early childhood development is considered to be most important phase in child's life which determine the quality of health well being, learning and behaviour across the life span, particularly during toddler stage. It is the time between infancy and childhood where a child learns and grows in many ways. It is a period of great opportunity but also easily prone to many disease, So proper child care should be taken.

Kuzhanthai Maruthuvam is one among the treasures of siddha system exclusively dealing with disease which affects children. It is the collection of abundant medicine that pacifies the deranged humor paving way for healthy childhood thus laying a concrete pillar for healthy society. Children between age 1 to 3 are easily prone to disease due to dietary habit of mother or of the child, if the baby has started consuming solid foods.

These days working women may find difficult to maintain good feeding frequency so as to fulfil the child's need as they are not available to feed often when the child requires, which leads to supplementary foods and increased the chance of indigestion. Other than this the altered food habits of the mothers also causes indigestion. Hence much care is really essential to prevent as well as to cure digestion problems in children.

Mantham is one of the diseases mentioned in Balavagadam and it is classified into 21 types. It illustrates that when mother feeds baby after having foods like mangoes, jack fruit and oily foods etc, may affect child's health mentally and physically.

As per siddha literature kattu mantham is one among the 21 types of mantham. It is common in children between the ages of 1 to 3 years.

According to T.V.Sambasivampillai Tamil-English dictionary , kattumantham is a disease in children arising from constipation. It is marked by indigestion, stomach pain, cough, fever, yawning, perspiration etc. It may be correlated with dyspepsia in modern science.

Functional dyspepsia is defined as persistent or recurrent pain or discomfort centered in the abdomen, without evidence of organic disease. It is a functional disease in which the gastrointestinal organ primarily the oesophagus, stomach, small intestine & colon function abnormally. The primary symptom of dyspepsia are upper abdominal pain, abdominal bloating, early satiety and these symptoms are most often provoked by eating.

The incidence of dyspepsia in children above one year is 85% in pediatric population. In the Out patient department of Ayodhidoss Pandithar hospital, National Institute of Siddha around 1500 patients are visiting every day for treatment for various ailments. Among them, 3 - 5% of patients are in pediatric group and are mostly affected by common digestive problems. As no objective structural or pathophysiological measure exists to assess outcome one has to rely on the subjective reporting of symptoms by the patients and their impact on normal daily activities to decide whether a treatment intervention is of benefit or not.

In Balavagadam, there is a Sastric Siddha formulation seenthil kudineer for KattuMantham(dyspepsia) which is also mentioned in Gunapadam mooligai vaguppu. The main ingredients of the seenthil kudineer are seenthil, sukku, sivathai which are known for their stomachic, carminative, laxative action. It is said to be cost effective also but efficacy of this medicine is not yet scientifically validated. Hence, I have selected Seenthilkudineer for my clinical trial.

## **2. AIMS AND OBJECTIVES:**

### **Primary Aim and Objectives:**

To evaluate the efficacy of seenthil kudineer for the management kattu mantham in Children under the following preclinical and clinical parameters

- ❖ Physico – chemical Analysis, , Carminative studies, Chemical analysis of trial drug
- ❖ Clinical studies

### **Secondary objectives:**

- ❖ To collect and review the ideas mentioned in the ancient Siddha literature about the disease kattu mantham.
- ❖ To explore Definition, Etiology, Clinical features, Diagnosis, Investigations and treatment of kattu mantham as laid down from various siddha literature.
- ❖ To make the correlative study of the siddha and modern aspect of this diseases.

## SIDDHA ASPECT

### மாந்தம்

#### வேறுபெயர்கள்

மந்தம், அலசம், அலசகம் என பிள்ளைப் பிணி மருத்துவ நூலில் குறிப்பிடப்பட்டுள்ளது.

#### இயல்

மந்த இயல்புடையது மாந்தம் எனப்படும். மந்தம் என்பது உருவ நிலையில் உடல்நிலையில் மந்தம். அருவநிலையில் அகக்கருவிகளாகிய மனம், புத்தி, சித்தம், அகங்காரம் ஆகிய அனைத்து அந்த கரணங்களிலும் மந்தம் என குழந்தை மருத்துவத்தில் கொடுக்கப்பட்டுள்ளது.

உண்ட உணவு செரியாமல் வயிற்றில் புளித்து வயிறு உப்பி இரைந்து மந்தத்தை உண்டாக்கி வாந்தியையும் கழிச்சலையும் உண்டாக்கி துன்பத்தை ஏற்படுத்தும் நோய் என பிள்ளைப் பிணிமருத்துவத்தில் குறிப்பிடப்பட்டுள்ளது.

#### நோய் வரும் பருவம்:

தாலப்பருவம், சப்பாணிப் பருவம், முத்தப் பருவம், வருகைப் பருவங்களில் உண்டாக்கக்கூடிய நோயாகும்.

குழந்தையின் முதல் ஆண்டில் இருந்து மூன்று ஆண்டுகள் வரை தொடரும் என குழந்தை மருத்துவம் மற்றும் தன்வந்திரி குழந்தை வாகடத்தில் குறிப்பிடப்பட்டுள்ளது.

இந்நோய் 3 மாதம் முதல் 12 வயது வரை வரக்கூடியது. பால் மட்டுமே குடிக்கும் பருவம், பாலும், சோறும் உண்ணும் பருவம், சோறு மட்டுமே உண்ணும் பருவம் ஆகிய மூன்று பருவங்களிலும் மாந்தம் ஏற்படும் என பிள்ளைப்பிணி மருத்துவத்தில் குறிப்பிடப்பட்டுள்ளது.

#### நோய் வரும் வழி

- நீர் நிலைகளில் பழுத்து, உதிர்ந்த சருகுகள் விழுந்து அழுகியிருக்கும் நீரைக் குடித்தல்.
- எருமைப்பால், புளித்த எருமைமோர், எருமை நெய். வாழைப்பழம், மாம்பழம், தேங்காய், இளநீர், கடலை, வெல்லம், காட்டுத் துவரை, மொச்சைக்கொட்டை, புளியங்கொட்டை, பருப்பு உருண்டை, மாவினால் செய்யப்பட்ட பொருட்கள், அதிரசம், வாயுப்பொருட்கள், சோறு இவைகளை அதிகமாக உண்ணல் முதலிய காரணங்களால் மாந்த நோய் உண்டாகும் என குழந்தை மருத்துவம் குறிப்பிடுகிறது.
- மந்தப் பொருளாகிய எருமைப்பால், நெய், வாழைப்பழம், மாம்பழம், கடலை, வெல்லம், மாமிசம், பருப்பு உளுவை மீன், வரால் மீன், கெண்டை ஆகியவற்றை குழந்தைகள்

உண்ணும்போது மாந்தநோய் உண்டாகும் என தன்வந்திரி குழந்தை வாகடம் கூறுகிறது.

- பாகற்காய், சுரை, உளுந்து, ஊன், பெரிய உளுவை மீன், வாளைமீன், பன்றி இறைச்சி, விரால்மீன், கெண்டை மீன் ஆகிய ஆகாத பொருட்கள் உண்பதாலும், மாந்தநோய் உண்டாகும் என பிள்ளைப்பிணி மருத்துவம் குறிப்பிடுகிறது.
- மேலும் சோறு மட்டுமே உண்ணும் குழந்தையின் உணவு குற்றத்தினாலும் உணவின் வேறுபாட்டாலும் மாந்தம் ஏற்படும்.
- குழந்தையின் துய்மையற்ற தன்மை, சரியான நேரத்தில் சாப்பிடாது நேரந்தவறி சாப்பிடல், சுத்தமற்ற உணவுப் பொருட்களைச் சாப்பிடல், உடம்பில் போதிய ஊட்டச்சத்து இல்லாத நிலை ஆகிய காரணங்களினாலும் இப்பருவத்தில் இந்நோய் வரும்.
- உணவினால் மட்டுமின்றி செயலின் வேறுபாட்டாலும் மாந்த நோய் குழந்தையைத் தாக்கும். வறுமை, பசி, துயரம், மனக்கவலை, பயம், கோபம், இச்சை போன்ற உணர்வுகளால் குழந்தையானது தாக்குறும் போது உணவுச்செரிக்கும் தன்மையில் மாறுபாடு நிகழ்ந்து மாந்தம் உண்டாகிறது என பிள்ளைப்பிணி மருத்துவம் கூறுகிறது.
- மேதிப்பால், நெய், கதலிப்பழம், தேங்காய், இளநீர், வெல்லம், புளித்த மோர், மாமிசம், கனிகள், உளுந்து, மொச்சை, புளியங்கொட்டை, உளுவை, கெண்டைமீன், பாகல், சுரை முதலான வாயுப் பண்டங்களை பால் கொடுக்கும் மாதர்கள் மிகுதியாக உண்டால் அல்லது குழந்தைகள் அதிகமாக உண்டால் மாந்த நோய் உண்டாகும் என ஆவி அளிக்கும் அமுத முறை சுருக்கத்தில் குறிப்பிடப்பட்டுள்ளது

#### நோய் வகைகள்

குழந்தை மருத்துவத்தில் மாந்த நோய் 21 வகைகளாகப் பிரிக்கப்பட்டுள்ளது

1. வளி மாந்தம்
2. அழல் மாந்தம்
3. ஐயம் மாந்தம்
4. விடல் மாந்தம்
5. போர் மாந்தம்
6. வாலை மாந்தம்
7. சுரம் மாந்தம்
8. நீர் மாந்தம்
9. செரியா மாந்தம்
10. கட்டு மாந்தம்
11. பால் மாந்தம்
12. எரி மாந்தம்
13. துளை மாந்தம்
14. துலை மாந்தம்

15. கணம் மாந்தம்
16. வலிப்பு(இழுப்பு) மாந்தம்
17. சுழி மாந்தம்
18. முக்கு மாந்தம்
19. சந்நி மாந்தம்
20. ஊதல் மாந்தம்
21. வீக்கம் மாந்தம்

இது தவிர மேலும் 10 வகை குறிப்பிடப்பட்டுள்ளன.

1. உப்பல் மாந்தம்
2. வாந்தி மாந்தம்
3. வறட்சி மாந்தம்
4. திட்டு மாந்தம்
5. உளை மாந்தம்
6. அக்கரம் மாந்தம்
7. பேய் மாந்தம்
8. நீர்கணம் மாந்தம்
9. தோடம் மாந்தம்
10. கருப்பம் மாந்தம்

எனவும் மற்றொரு வகைப்பாட்டின் படி, எண்வகை மாந்தம் கீழ்க்கண்ட வகைகள் கொடுக்கப்பட்டுள்ளது.

1. பொது மாந்தம்
2. செரியா மாந்தம்
3. தலை மாந்தம்
4. போர் மாந்தம்
5. கட்டு மாந்தம்
6. விட மாந்தம்
7. நீர் மாந்தம்
8. சுழி மாந்தம்

**தன்வந்திரி பாலவாகடத்தில்** மாந்தநோய் 21 வகைகளாக வகைப்படுத்தப்பட்டுள்ளது

1. அழல் மாந்தம்
2. ஊதல் மாந்தம்
3. எரி மாந்தம்
4. ஐயம் மாந்தம்
5. கணம் மாந்தம்
6. சந்நி மாந்தம்

7. சுரம் மாந்தம்
8. சுரி மாந்தம்
9. செரியாமை மாந்தம்
10. தலை மாந்தம்
11. துலை மாந்தம்
12. நீர் மாந்தம்
13. பால் மாந்தம்
14. போர் மாந்தம்
15. முக்கு மாந்தம்
16. வலிப்பு மாந்தம்
17. வளி மாந்தம்
18. வாலை மாந்தம்
19. விடம் மாந்தம்
20. வீக்கம் மாந்தம்

**அனுபவ வைத்திய தேவரகசியத்தில் 8 வகைகள்:**

1. செரியா மாந்தம்
2. பீர் மாந்தம்
3. சுர மாந்தம்
4. விஷ மாந்தம்
5. சுழி மாந்தம்
6. ஊது மாந்தம்
7. நீர் மாந்தம்
8. தலை மாந்தம்

**மதலை நோய் நூலில் மாந்தம் 13 வகைகளாகப் பிரிக்கப்பட்டுள்ளது.**

**(கும்ப முனி பாலவாகடம்)**

“தோன்றிய வாத பித்தம் சொல்லிய சிலேற்ப மாந்தம்

ஊன்றியதடுக்கு மாந்தம் விச மாந்தம் போர் மாந்தம் தான்

கன்றியபால் மாந்தம் வன்கப மாந்தம் பொது மாந்தம் பின்

வந்திடும் வினையாம் சன்னி வலி சர்த்தி பதிமூன்றாதாமே”

**அவையாவன:**

1. வாத மாந்தம்
2. பித்த மாந்தம்
3. சிலேற்பன மாந்தம்



4. நடுக்கு மாந்தம்
5. விஷ மாந்தம்
6. போர் மாந்தம்
7. பால் மாந்தம்
8. வன்கப மாந்தம்
9. பொது மாந்தம்
10. வினை மாந்தம்
11. சன்னி மாந்தம்
12. வலி மாந்தம்
13. சாத்தி மாந்தம்

**பிள்ளைப்பிணி மருத்துவம் :**

**Definition:**

Indigested food in the stomach causes abdominal distension and manifests as Mantha Noi with vomiting and diarrhoea.

“மந்தமது வரலாறு சொல்லக் கேளீர்  
மாதரோடு பாலகரு மருந்துந் தீனி  
சேர்ந்ததொரு பால்தனிலே விசந்தான் கொண்டு  
சிறுவருக்கு உதரத்தில் மந்தம் பற்றி  
ஊர்த்தெழுந்த திரையினால் விரணங்கொண்டு  
உள் விரணம் பல நோவு உறவ தாகி  
சார்ந்த மலம் சிக்கியதில் தோச முண்டாய்  
தானெழும்பும் மாந்தவகை சாற்று வேனே”

--பிள்ளை பிணி மருத்துவம்

The above verse states that Mantham occurs in children due the diet taken by the mother and the child, which causes indigestion and other related diseases. According to the Pillai Pini Maruthuvan text, Mantham occurs from the age of 3 months to 12 years in children. particularly while child having breast milk(Exclusive Breast Feeding), then weaning period during which both milk and solid foods were given and later stage where the child given solid feeds (late weaning period).

During the period of exclusive breast feeding if the mother takes food which is not digestable in large amounts. The child becomes affected by Mantha Noi due the intake of mother's devitalized milk. The psychological feelings of the mother also affects the quality of milk given to the child.

During the weaning period, due to the diet taken by both the mother and the child causes Mantha Noi. The psychosomatic feelings of mother like hunger, poverty, anger, fear, desire affects the efficacy of the milk fed to the child in this period.

During the late weaning period, the disease occurs mainly due to the improper food habits of children like taking not easily digestable foods, taking cleanless foods, taking irregular meal and taking imbalanced diet. Malnourished children are also affected by Mantham.

**பிள்ளைப்பிணி மருத்துவம் பாகம் 2ல் மாந்தத்தின் வகைகள்- 53**

**In Pillai Pini Maruthuvam part 2 (Types 43)**

1. Adai Mantham
2. Atcha Akkara Mantham
3. Azhal Mantham
4. Allu Mantham
5. Eluppu Mantham
6. Uppal Mantham
7. Uppu Mantham
8. Ulai Mnatham
9. Oothu Mantham
10. Eri Mantham
11. Iya Mantham
12. Kattu Mantham
13. Kana Mantham
14. Karppa Mantham
15. Kanai Mantham
16. Kal Mantham
17. Kazhi Mantham
18. Sakthi Mantham
19. Sanni Mantham
20. Sanni Bhatha Mantham
21. Sura Mantham
22. Suzhi Mantham
23. Seriya Mantham

24. Thalai Mantham
25. Thittu Mantham
26. Neer kana Mantham
27. Thulai Mantham
28. Neer Mantham
29. Pal Mantham
30. Pul Mantham
31. Bethi Mantham
32. Pei Mantham
33. Por Mantham
34. Maladi Mantham
35. Mukku Mantham
36. Valippu Mantham
37. Vali Mantham
38. Varatchi Mantham
39. Vanthi Mantham
40. Val Mantham
41. Vida Mantham
42. Thoda Mantham
43. Veekka Manthamare described.

43 வகை மாந்தங்கள் குறிகுணங்களுடன் காணப்படுகின்றன.

மீதமுள்ள10 மாந்தங்கள் பெயரளவில் மட்டும் வகைப்படுத்தப்பட்டுள்ளது.

**குழந்தை மருத்துவத்தில் மாந்தத்தின் பொது குறிகுணங்கள்:**

- ❖ குழந்தையின் உடம்பு சோர்ந்து இருத்தல்
- ❖ உடம்பு நோதல்
- ❖ மிகுதியான வியர்வை உண்டாதல்
- ❖ சுறுசுறுப்பாக இல்லாமல் கண்விழி சிவந்திருத்தல்
- ❖ கண்கள் குழி விழுந்து காணல்
- ❖ முகம் வெளுத்து ஒரு வகை மங்கிய ஒளி காணல்

- ❖ குரல்தளர்ந்து வாய்உலர்ந்துகாணல்
- ❖ ஆடிக்கடி வாந்தி ஏற்படல்
- ❖ புசி இன்மை காணல்
- ❖ சீதமும் மலமுமாகவும், கெட்டுபோன பால் போவுலம், தண்ணீர் போலவும் பல நிறமாக பேதியாதல்
- ❖ கை கால்கள் குடு இல்லாமல் குளிர்ந்து காணல்

#### கட்டு மாந்தக் குறிகுணம்

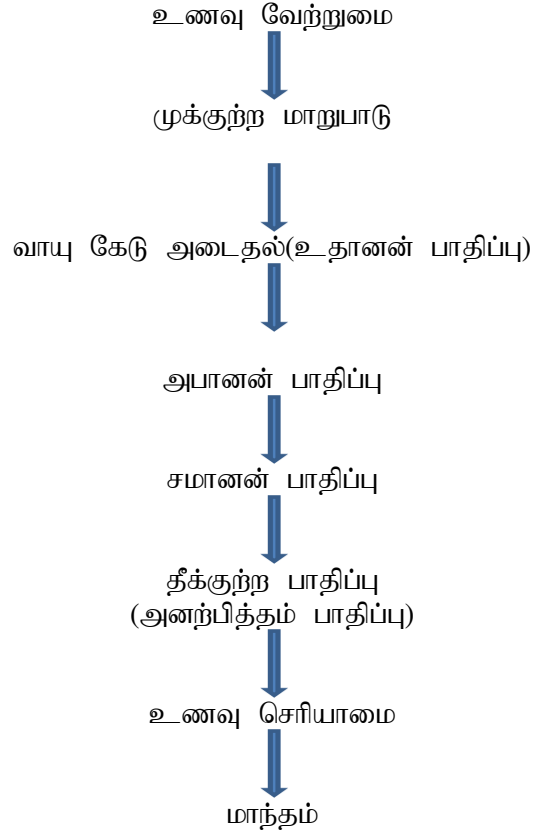
“தாயார் முலையில் வாய்வைத்துச்  
சற்றே யுண்ணும் திகைத்திருக்கும்  
ஓயா தழுகை சிற்றிருமல்  
உள்ளே சுரமு மிகவுண்டாம்  
சேயா மலமுஞ் சலங்கட்டிச்  
சிக்கப் பண்ணும் பசியில்லை  
மாயா மசக்கு மிதுகட்டு  
மாந்த மென்று வகுத்தனரே”

-பாலவாகடம்

#### குறிகுணம்

1. மலம் சலம் கட்டுபடும்
2. சற்றே பாலுண்ணும்
3. பசியின்மை
4. சுரம்
5. கொட்டாவி
6. சிற்றிருமல்

## முக்குற்ற வேறுபாடு



## முக்குற்ற நிலைகள்:

### A. Vali:

**Site of vadham in body:** வாதம் வாழுமிடம்

Abaanan, faces idakalai, below the umbilical region, spermatic cord, pelvic bones, skin, nerve plexus, joints, hair follicle, muscle, alimentary tract, bones, ear and thighs.

மேலும்:

“அறிந்திடும் வாத மடங்கு மலத்தினில்”- திருமூலர்

“நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய்

நாபிக்குக் கீழென்று நவில லாகும்” - யூகி முனிவர்.

என்பதால் மலமும், நாபிக்கு கீழிடமும் வாதமிருக்குமிடங்கள் என கொள்ளலாம்

சித்தமருத்துவாங்கசுருக்கம்(ப.எண்.139)

## **Vadham consists of 10 types**

### **1. Praanan: (Uyirkaal)**

This controls knowledge, mind and five sense organs, which are useful for breathing and digestion.

### **2. Abaaban: (Keezh nokkung kaal)**

This is responsible for all down ward movement such as passing urine, stools, semen, and menstrual flow. Abaanan vayu is affected in Kattu mantham due to constipation

### **3. Samaanan: (Nadukkaal)**

This aids in proper digestion and controls other vayus. In Kattu mantham, this vayu is altered leading to poor appetite and cannot control the other vayus.

### **4. Viyaanan: (Paravukaal)**

This is responsible for all movements of all parts of the body and distribution of saaram. This vayu is affected in Kattu mantham because of decreased activity due to symptoms like constipation.

### **5. Uthaanan: (Mel Nokkung kaal)**

Responsible for all upward movements such as vomiting and nausea. It distributes the saaram equally to all tissues. It is affected in Kattu mantham because of unequal distribution of saaram and presence of cough

### **6. Naagan:**

Responsible for opening and closure of eye lids

### **7. Koorman:**

Responsible for vision and yawning. .

### **8. Kirukaran:**

This is responsible for salivation, nasal secretion, sneeze, cough and maintains the appetite. In Kattu mantham, this vayu is affected due to presence of cough and poor appetite.

### **9. Devathatthan:**

This is responsible for tiredness (Laziness), anger and emotional expression. This vayu is deranged in Kattu mantham because some patient had tiredness.

### **10. Dhananjeyan:**

It produces swelling of the body after death. It escapes on the third day after death bursting out of the cranium.

சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.142 - 149)

## ii. Azhal:

### Sites of pitham in body:

Pinkalai, praanavayu, urinary bladder, moolakkini, heart, head, umbilical region, stomach, sweat, saliva, blood, saaram, eyes and skin.

“பிரிந்திடும் பித்தம் பேராம் சலத்தினில்” - திருமுலர்

“போமென்ற பித்தத்துக் கிருப்பிடமே கேளாய்

பேரான கண்டத்தின் கீழே தாகும்” - யுகிமுனிவர்

கூறியிருப்பதனால் சிறுநீரும், கண்டத்தின் கீழிடமும் பித்தம் இருப்பிடமாகும்.

சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.153)

## Pitham consists of 5 types

### 1. Anal pitham:

It promotes appetite and helps in digestion. In Kattu mantham, it is affected due to presence of poor appetite.

### 2. Ranjagam:

It gives colour to the blood. In Kattu mantham, some children are anaemic.

### 3. Saadhagam:

It is important for day today activities with the help of mind and brain.

### 4. Praasagam:

It gives complexion to skin.

### 5. Aalosagam:

It brightens eyes and responsible for clear vision.

- சித்த மருத்துவாங்க சுருக்கம் (ப.எண்.155-157)

## iii. Iyam:

### Sites of Kabam in body:

Kabam (or) kapham is located in sammana vayu suzhumunai, sperm, head, tongue, uvula, fat, bone marrow, blood, nose, chest, nerve, bone, brain, large intestine, eyes, and joints and also present in throat, stomach and pancreas.

- சித்த மருத்துவாங்க சுருக்கம் (ப.எண்.158)

## **Kabam consists of five types**

### **1. Avalambagam:**

It lies in the lungs. It controls the heart and other four kabams.

In Kattu mantham, it is deranged due to presence of cough.

### **2. Kilethagam:**

It lies in the stomach and gives moisture to food material and also helps for digestion.

In this disease, it is affected because of the poor appetite present in children.

### **3. Pothagam:**

It lies in tongue and responsible for taste sensation.

### **4. Tharpagam:**

It is present in the head and responsible for coolness of both eyes.

### **5. Santheegam:**

It is present in joints. Responsible for lubrication and free movements of joints.

- சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.161 - 163)

## **PINIYARI MURAIMAI: (DIAGNOSIS)**

Piniyari muraimai is a method of diagnosing a disease. The way of diagnosis is very important to the physician who deal the disease, because of that only he or she can point out the cause of disease.

இதனையே திருவள்ளுவர் திருக்குறளில் பின்வருமாறு கூறுகிறார்

“நோய்நாடி நோய்முத னாடியது தணிக்கும்

வாய்நாடி வாய்ப்பச்செயல்”- திருக்குறள்

Siddha system has a very unique method for diagnosis. This is based upon three principles.

1. Poriyaal arithal (Inspection)

2. Pulanaal arithal (Palpation)

3. Vinaathal (Interrogation)



### **I. Poriyaal arithal:**

Porigal means the five sense organs. These are eyes, ears, nose, tongue and skin. Poriyaal arithal is examining the five sense organ of the patient by the five sense organ of the physician.

#### **In kattu mantham,**

Mei (skin)	-	Normal
Vaai (Tongue)	-	Normal
Kann (Eye)	-	Normal
Mookku (Nose)	-	Normal
Sevi (Ear)	-	Normal

### **II. Pulanaal arithal:**

Pulan means sense of perception from the five sense organs. That means understanding by the sense objects.

#### **In Kattumantham,**

Ooru (sensation)	-	Normal
Oosai (sound)	-	Normal
Oli (vision)	-	Normal
Suvai (Taste)	-	Normal
Naatram (smell)	-	Normal

### **III. Vinaathal:**

Vinaathal means the physician should know about the patients name, age, occupation, family history, socio-economic status, diet and habits, complaints, relevant to disease in his family by asking questions.

**Ezhu udar kattugal and Ennvagai thervugal also used for diagnosing a disease in Siddha system**

#### **Ezhu udar kattugal:**

1. Saaram
2. Senneer
3. Oonn
4. Kozhuppu

5. Enbu
6. Moolai
7. Sukkilam/suronitham

When the seven udar kattugal increase or decrease from the normal level, the normal functions of the body will be affected.

**In kattu mantham.**

- |                            |   |  |
|----------------------------|---|--|
| a. Saaram                  | : | Deranged due to poor appetite causing tiredness.   |
| b. Senneer                 | : | Deranged in some patient with nutritional anaemia. |
| c. Oonn                    | : | Normal   |
| d. Kozhuppu                | : | Normal   |
| e. Enbu                    | : | Normal   |
| f. Moolai                  | : | Normal.  |
| g. Sukkilam/<br>Suronitham | : | Normal   |

**The diagnostic value of Enn vagai thervugal is specific to siddha system of medicine.**

**Enn vagai thervugal are:**

1. Naadi (Uyir thathu)
2. Sparisam (Touch feel sensation)
3. Naa (Tongue)
4. Niram (Colour of the skin)
5. Mozhi (Quality and character of speech)
6. Vizhi (Eye)
7. Malam (Stools)
8. Moothiram (Urine)

## Naadi (Uyir thathu) :

Envagai thervugal is the basic diagnostic principles and the uniqueness of the siddha system of medicine. The following lines are said about this.

“மெய்க்குறி நிறந்தொனி விழி

நாவிருமலம் கைக்குறி”

-சித்த மருத்துவாங்க சுருக்கம்<sup>5</sup>(ப.எண்.483)

Otherwise known as uyir thathu, is the principle method for diagnosis in siddha system. The naadi indicates the status of the body thathus and whether the body is normal or abnormal. It is responsible for existence of life in the physical body. It is said in literatures as உடலில் உயிர்தரித்திருப்பதற்கு காரணமான சக்தி எதுவோ அதுவே “தாது அல்லது நாடி” எனப்படும்.

“நாடிப்பரிசம் நாநிறம் மொழிவிழி

மலம் முத்திரமிவை மருத்துவ ராயுதம்”

- நோய் நாடல் நோய் முதனாடல் ப.எண். 270)

In childrens the naadi nadai is not clearly seen. This is indicated by following lines,

“கொண்டிடவே கயரோகி காசரோகி

குறிப்பாகச் சிற்றின்பம் செய்த பேர்கள்

அண்டிடவே தரித்திரர்கள் விருத்தர் பாலர்

அன்பாகத் தண்ணீரில் முழுகினோர்கள்

கொண்டிடவே இவர்களது உறுப்பின் தாது

கூறவே முடியாது எவர்க்குக் கிடும்”

- நோய்நாடல் நோய் முதனாடல் (ப.எண்:171).

-

### b) Sparisam: (Touch feel sensation)

Identify the heat or coldness of the body, pain and skin nature (soft or hard)

In kattu mantham,

- It may be hot due to fever.
- It may be cold due to sweating.

**c) Naa: (Tongue)**

It is noted for colour of the tongue local lesion (ulceration, redness), coating deposition of tongue and dryness of the tongue.

**d) Niram: (Colour of skin)**

Colour of skin, conjunctiva, teeth, tongue, nail bud and hair are note In Kattu mantham, Conjunctiva, nail bud may be pale due to nutritional anaemia.

**e) Mozhi : (Quality and character of speech)**

Observation of speech and voice. This is said in Agasthiar vallathi as

“வார்த்தையைப் பார்”

In Kattu mantham normal voice is present.

**f) Vizhi : (Eye)**

By this examination, colour of eye (redness, pallor) protrusion, tears, excreta of eye, disease of eyes are noted.

In Kattu mantham, the eyes of Some patients have pallor of lower eyelid due to nutritional anaemia.

**g) Malam : (stools)**

Consistency of stool will be like hard pellets like, foul smell, decreased frequency of defeacation, constipation, lesser quantity of stool are noted.

In Kattu mantham, patient have hard pellets like stools and decreased frequency of passing stools.

**h) Moothiram : (Urine)**

Colour of urine (yellow, black, white copper colour, mixed colour. Then smell of urine (smell of fire, honey, sweet odours, fruity odour) frothy or not, decreasesd frequency of urination and quantity of urine are noted.

In Kattu mantham, there will be normal straw yellow colour of urine with decreased frequency of urine.

### Neer nira kuri and Nei kuri:

This urine examination is unique in Siddha system of Medicine

#### நீர்நிறக்குறி:-

“அருந்து மாறிரதமும் அவிரோதமதாய்  
அகல் அலர்தல் அகாலவூன் தவிரந்தழற்  
குற்றளவருந்தி உறங்கி வைகறை  
ஆடிக்கலசத் தாவியே காது பெய்  
தொருமுகூர்த்தக் கலைக்குட்படு நீரின்  
நிறக்குறி நெய்க்குறி நிறமித்தல் கடனே”

- நோய் நாடல்நோய் முதனாடல் (ப.எண். 282)

#### Collection of sample urine:-

The patient must take well cooked food in the previous day. Food intake should be taken at correct time and avoid excessive intake. The urine is collected on the dawn of the next day in a pure glass container and closed immediately to prevent contamination. This specimen must be examined within one and half hours from the collection.

#### நெய்க்குறி:-

“நிறக்குறிக் குரைத்த நிருமாண நீரிற்  
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடு விடுத்  
தென்றுறத் திறந்தொலி ஏகாதமைத்ததி  
னின்றதிவலை போம் நெறி விழியறிவும்  
சென்றது புகலும் செய்தியை யுணரே”

- நோய் நாடல் நோய் முதனாடல் (ப.எண். 298)

A drop of gingelly oil is dropped on a wide glass vessel containing the urine to be tested which is kept under sunlight in a calm place. The derangement of three dhoshas can be diagnosed by the mode of spread of gingelly oil on the surface of urine.

In Kattumantham the results of nei kuri is snake like oil floating on urine in some patients and ring like structure on urine in some patients.

**MARUTHUVAM:**

The treatment in siddha medicine is aimed at keeping the Mukkutram in the state of equilibrium.

i.e,

- Highly vitiated vatham to normal level
- Vitiating pitham to normal level
- Vitiating kabam due to vitiated vatham to normal level.
- To strengthen the seven udar kattugal and maintains the normal level.

Keeping in mind the need for bringing out an effective therapy for Kattu mantham with the Seenthil kudineer.

**Line of treatment:**

Siddha treatment is not only for to cure the disease but also teaches prevention and rejuvenation concepts.

Saint Thiruvalluvar says about the duty of a physician as follows

“நோய்நாடி நோய்முத னாடியது தணிக்கும்

வாய்நாடி வாய்ப்பச்செயல்”– திருக்குறள்

“உற்றான் ளவும் பிணியளவுங் காலமுங்

கற்றான் கருதிச் செயல்”– திருக்குறள்.

From the above verse, it is essential to know the etiology, the nature of patients, severity of the illness, the seasons and the time of occurrence the disease must be observed clearly.

**Line of treatment is as follows:**

1. Kaappu (prevention)
2. Neekkam (Treatment)
3. Niraivu (Restoration)

## 1. Kaappu: (prevention)

Prevention is the main aim of siddha system. Siddhars have described general preventive measures and special measures.

Especially in Balavagadam, special preventive measures said for prevention of disease of the child. It starts from the conception and goes on the child grows up in intra uterine life and after delivery. ie diet of pregnant women, her habits, medicine to take in every month of pregnancy, her psychological conditions and surroundings.

## 2. Neekkam: (Treatment)

The aim of treatment is based on

- To bring the three thodams into normal equilibrium state.
- To treat the patients according to the symptoms by internal medicine Seenthil kudineer

### i. Anupanam in Siddha system :

“அனுபானத்தாலே யவழ்தம் பலிக்கும்,  
இனிதான சுக்கு கன்னல் இஞ்சி – பினுமுதகால்  
கோமேயம் பால் முலைப்பால் கோநெய் தேன் வெற்றிலை நீர்,  
ஆமிதை யாராய்ந்து செய்யலாம்”

- தேரையர் வெண்பா

Siddha system considers anupanam as an important. It is otherwise known as “Thunai marunthu”, it can be translated as vehicle, adjuvant and supporting to drug therapy. Without anupanam, success in the treatment is mostly not possible.

### ii. Pathiyam:

During the course of treatment, the patients were advised to follow certain restrictions regarding diet and physical activities.

This type of medical advice termed as pathiyam. Importance of pathiyam is said by Siddhars Theraiyar as follows,

“பத்தியத்தினாலே பலனுண்டாகும் மருந்து

பத்தியங்கள் போனால் பலன் போகும் - பத்தியத்தில்

பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால்

பத்தியமே உத்தியென்று பார்”

- தேரையர் வெண்பா.

The patient with Kattu mantham is advised to avoid spicy and hot food , contaminated water , junk foods .

### 3. Niraivu: (Restoration)

- Reassurance of disease recovery was given to all patients.
- All the patients are advised to prepare for lifestyle changes that provides a disease free life.

#### Diet:

Siddhars advise the diet regimens for Kattu mantham patients. They are explained below:

“கத்திரி பேய்புடல வரை யிருபாகல் பருங்காளா கண்டகாரி

அத்திக் காய்களும் வருக்கைமாயற்றை கரையால் பீர்க்கரும் பிஞ்சுவேர்

மொய்த்த சூரணங் கதலித் தண்டுகளைப் பூமுளங்கி முருக்கரும்பும்

அத்தி பூசணிக் காயருள்ளி வள்ளியுங் கபத்தோர்க் காணாமே”

- பதார்த்த குண சிந்தாமணி.

“வேளை மணத்தக்காளி மென்சீதை சக்கரவர்த்தி

பீளை வசலை சுக்கு பெண்கணங்கள் - வேளையில்

செந்தளிர் களைக்கீரை செய்வர் கபதேகர் நிதம்

வந்தளியுணத்தான் மகிழ்ந்து”

- பதார்த்த குண சிந்தாமணி.



**காய்கறிகள்:-**

- கத்தரி
- பேய்புடல்
- அவரை
- கண்டங்கத்திரி
- அத்திக்காய்
- பீர்க்கு
- வாழைத்தண்டு
- முருங்கை
- பாகல்
- பூசணி

**வேர்க்கிழங்குகள்:-**

- முள்ளங்கி
- ஈருள்ளி

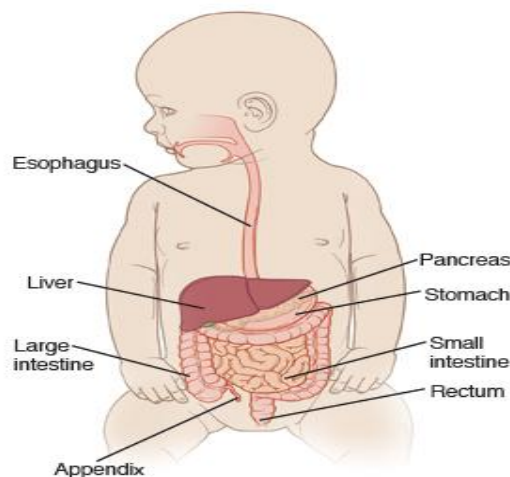
**கீரைகள்:-**

- மணத்தக்காளி
- சிறுகண்பீளை
- வசலை
- சிறுகீரை
- பொன்னாங்கன்னி
- சக்கரவர்த்தி கீரை
- சுக்கு கீரை ஆகியவைகளை உணவில் சேர்த்துக் கொள்ளவேண்டும்.

## MODERN ASPECTS

### GASTROINTESTINAL TRACT:

The GI tract is the pathway where food passes from the mouth, through the esophagus, stomach, small and large intestine within where the nutrients are extracted for the needs of the body. The residue then passes to the rectum where it is evacuated.



### ANATOMY OF THE GASTROINTESTINAL TRACT:

#### 1. The Esophagus:

The first part of the pathway of GIT is the esophagus, which guides food from the mouth, where it is prepared by chewing, down to the stomach where it is stored.

#### 2. The Stomach:

The stomach is both a storage space, holding as much as a quart and a half of ingested food, and a secretory organ that produces the gastric acid necessary for digestion. However, the stomach does not absorb food. When food enters the stomach from the esophagus it remains for a short period while it is mixed with gastric acid. The stomach then by involuntary muscle contractions (peristalsis) empties the food gradually into the duodenum, the first part of the small intestine.

#### 3. The small Intestine:

The small intestine consists of three parts: the duodenum, the jejunum and the ileum. In these three parts, certain digestive secretions are mixed with food, and the nutrients are absorbed into the blood stream.

**The Duodenum:**

The duodenum treats the food it receives with bile from the liver and enzymes from the pancreas. It also adds liquid duodenal fluid that comes from the wall of the duodenum itself. The food, bile, enzymes and liquids brought together in the duodenum are then passed into the jejunum

**II. The Jejunum :**

The jejunum or second portion of the small intestine is approximately 10 feet long. It lies immediately behind the duodenum and continues the process of digestion, breaking down food into essential elements

**III. The Ileum:**

The ileum or third portion of the small intestine, like the jejunum, is about 10 feet long. It is here that a major part of the absorption of food products and liquids occurs. Waste products of the digestive process are passed from the small intestine or terminal ileum, into the large intestine, also known as the colon.

**4. Large Intestine (colon):**

The colon moves waste products through about four feet by the continuing process of undulating motions or peristalsis, which is common to all parts of the gastrointestinal tract. The primary function of the colon is to store waste products of digestion prior to evacuation. The colon absorbs small amounts of water and electrolytes.

**COMMON GASTROINTESTINAL TRACT DISORDER:**

Functional gastrointestinal disorders are common in children. Our brain and our GI tracts are closely connected (the “mind-body connection”). Functional GI conditions are due to a combination of extra sensitivity of the GI tract, with changes in the motility or movement of the digestive system.

Functional gastrointestinal disorders is specifically manifested as abdomen pain ,vomiting, early satity,abdomeninal distention,constipation.

## **FUNCTIONAL DYSPEPSIA**

### **Definition**

Functional dyspepsia is defined as persistent or recurrent pain or discomfort centered in the abdomen, without evidence of organic disease. It is a functional disease in which the gastrointestinal organ primarily the oesophagus, stomach, small intestine & colon function abnormally. The primary symptoms of dyspepsia are upper abdominal pain, abdominal bloating, early satiety and these symptoms are most often provoked by eating

### **Description**

A functional GI disorder refers to a condition where the primary abnormality is an alteration in the way the body works (altered function), rather than an identifiable structural or biochemical cause. Gastrointestinal motility is defined by the movements of the digestive system, and the transit of the contents within it. When nerves or muscles in any portion of the digestive tract do not function normally, symptoms only persist. The disturbed motility present in functional dyspepsia leads to amplified sensation in the upper gut (visceral hyperalgesia).

### **Causes ;**

- Some foods like potatoes, chickpeas and other legumes, lentils, foods with lots of spices and oils do not get properly digested within the body, they can cause dyspepsia
- Some psychological causes like a child with temper tantrums who does not take food wholeheartedly.
- Microorganisms that live within the lining of the stomach can cause irritation which can interfere with the digestion process

### **Symptoms**

Functional Dyspepsia is due to uncoordinated and uneven emptying of the upper digestive tract. The vast majority of patients experience more than one symptom.

- Pain in belly
- Fullness and bloating of abdomen
- An inability to finish meals
- Heartburn,
- sour taste in the mouth,

- Excessive burping, nausea,
- Sometimes vomiting.
- Characteristically, these complaints are sporadic, poorly localized, and without consistent aggravating or relieving factors,
- Constipation and various foods or additives in the diet can worsen functional pain.

## **PATHOPHYSIOLOGY**

Functional dyspepsia is usually defined as chronic or intermittent upper abdominal symptoms for which no organic cause can be found. Division of functional dyspepsia into subgroups such as reflux-like, ulcer-like, dysmotility-like and non-specific dyspepsia has been proposed, but lack a scientific basis.

The major pathophysiological mechanism responsible for functional dyspepsia include psychosocial factors and alteration in motility and visceral sensation. Approximately 50% of patients with functional dyspepsia have motor disorders, such as impaired fundic relaxation, antral dilation and hypomotility.

Patients typically present with gastric hypersensitivity resulting from abnormal afferent function. The role of *helicobacter pylori* in functional dyspepsia is difficult to define. Impaired gastric and intestinal reflexes have also been observed in functional dyspepsia. In recent years other avenues of pathophysiology are also showing some interest in functional dyspepsia. Although both evidence are not sufficient to a significant genetic contribution to functional dyspepsia. Some evidence suggest an interaction between polymorphisms of genes responsible for components of the immune response and *Helicobacter pylori* infection among some patients with functional dyspepsia.

## **DIAGNOSTIC TESTS**

There are no specific diagnostic markers for functional dyspepsia. As with many other conditions, a thorough and detailed history taken by a physician is the most important component of the assessment and often leads to the correct diagnosis. The history needs to include dietary, psychological, and social factors.

A history may disclose a relationship between symptoms and food, activity, or stressors. It is often helpful for the child and parents to maintain a symptom diary detailing the time, location, intensity and character of the pain or discomfort, time and content of the meals, daily activities, and stool pattern.

Considerable diversity of opinion remains among physicians regarding the extent of diagnostic tests to perform in a child who seems to have a symptom constellation pointing towards a functional cause of the dyspepsia.

- The diagnostic procedure needs to be individualized, according to the information obtained during the history taking and the physical examination. An upper gastrointestinal endoscopy is not mandatory.
- Urine evaluation and blood evaluation to screen for other disease are usually necessary.
- Endoscopy allows the discovery of ulcerations or significant inflammation in the upper gastrointestinal tract
- If the endoscopy is normal, then it may be helpful to monitor for acid reflux (back flow of stomach contents into the esophagus).
- Abdominal ultrasonography does not appear to be helpful in children.
- Upper gastrointestinal x-rays with small bowel follow-through are useful to exclude physical causes such as malrotation [incorrect position of the intestine in the abdomen], terminal ileitis [Crohn's Disease], and other obstructive or inflammatory lesions.
- Gastro duodenal manometry is a feasible and useful diagnostic tool in the clinical investigation of children

#### **TREATMENT :**

The management of dyspepsia revolves around a structural or functional cause. If a structural cause is found, the treatment can be specific to the underlying cause. For functional dyspepsia, the aim is to provide symptomatic relief.

- Reduction or avoidance of spicy, fatty, or caffeine-containing food or drink may help if associated with symptom onset.
- Medications such as H<sub>2</sub>-blockers [reduce amount of acid produced in the stomach],
- proton pump inhibitors [limit amount of acid produced]
- Prokinetic agents such as metoclopramide, domperidone, cisapride or erythromycin [increase gastrointestinal motility], have been used with some success.
- There remains a proportion of children who may have a behavioral or psychological base to their complaint. For them, treatments such as
- Environmental modification,
- Relaxation techniques,

- Psychotherapy,
- Stress reduction,
- Hypnotherapy, or biofeedback have been used with variable success.

## **PROGNOSIS**

Functional dyspepsia may come and go and symptoms could present with increased severity for several weeks or months and then decrease or disappear entirely for some time

## **PREVENTION**

- To avoid or reduce heavy foods like cheese, yogurt, ice cream, peanut butter and bananas. Heavy foods overload the digestive system and cause problems like digestion, constipation, congestion and allergies
- As much as possible children should eat real food, not highly-processed food with lots of additives.
- Sodas and high-fructose corn syrup can harm digestion. Many childrens don't tolerate dairy , gluten or food additives.

## **DIFFERENTIAL DIAGNOSIS**

Other disorders can have symptoms that may be similar to or overlap with gastrointestinal functional or motility disorders in children. Significantly, these disorders have features that a doctor can identify, which distinguish them from functional gastrointestinal or motility disorders.

### **1. Hirschsprung's Disease**

#### **Definition**

Children with Hirschsprung's disease are missing the nerve cells (ganglion cells) within the wall of their colon or rectum. These cells are responsible for the normal wave-like motion of the bowel (peristalsis). When they are missing the stool stops and an obstruction occurs. the length of affected bowel varies. The most common transition point is in the upper rectum or the sigmoid colon.

Hirschsprung's disease is a congenital disease. That means a person is born with it. The disease may also be hereditary, which means a parent can pass it to a child.

## **Symptoms**

Symptoms usually begin within a few days after birth. But some people don't develop them until childhood or even adulthood.

In infants, the primary symptom is not passing meconium, an infant's first bowel movement, within the first 24 to 48 hours of life. Other symptoms include:

- Vomiting and abdominal distention as a newborn
- Chronic constipation
- More rarely diarrhea, fever, and distention (symptoms associated with enterocolitis – inflammation of the small intestine and colon).

Symptoms in older children include passing small watery stools, diarrhea, and a lack of appetite.

## **Diagnosis**

The diagnosis is made by a combination of barium x-rays and rectal biopsy. In a lower GI series, x-rays are used to measure the width of the colon and rectum. Rectal biopsy involves removing a piece of rectal tissue to learn whether the nerve cells that control intestinal muscle contractions are present. Rectal manometry, a test that involves recording pressure changes within the colon and rectum, is sometimes performed.

## **Treatment**

The treatment of Hirschsprung's disease is primarily surgical. The goal of surgery is to remove the abnormal bowel and attach the normal bowel to the anus just above the sphincter.

## **Irritable bowel syndrome**

### **Definition**

Irritable bowel syndrome is a disturbance of bowel function that includes symptoms of abdominal pain or discomfort and altered bowel habit (change in frequency or consistency) – chronic or recurrent diarrhea, constipation, or both in alternation. IBS comprises a group of functional bowel disorders.

"Irritable Bowel" refers to a disturbance in the regulation of bowel function that results in unusual nerve sensitivity and muscle activity.



## **Symptoms**

The symptoms of IBS include abdominal pain or discomfort and changes in bowel habits. To meet the definition of IBS, the pain or discomfort should be associated with two of the following three symptoms:

- Start with bowel movements that occur more or less often than usual
- Start with stool that appears looser and more watery or harder and more lumpy than usual
- Improve with a bowel movement

Symptoms may often occur after eating a meal. To meet the definition of IBS, symptoms must occur at least once per week for at least 2 months.

## DRUG REVIEW

### 1. CHUKKU - சுக்கு

<b>Botanical Name</b>	:	<i>Zingiber officinale</i>
<b>English Name</b>	:	Dried Ginger
<b>Family</b>	:	Zingiberaceae
<b>Part used</b>	:	Rhizome

### ORGANOLEPTIC CHARACTER

<b>Suvai</b>	:	Karppu
<b>Thanmai</b>	:	Veppam
<b>Pirivu</b>	:	Kaarppu

பொது குணம் :

சுக்கு

“குலைமந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை

மூலம் இரைப்பிருமல் முக்குநீர் - வாலகப

தோடதி சாரந் தொடர்வாத குன்ம நீர்த்

தோடம் ஆமம்போக்குஞ் சுக்கு”

(அகத்தியர் குணவாகடம்)

### ACTIONS:

- Stimulant
- Carminative
- Stomachic

### CHEMICAL CONSTITUENTS:

- Camphene
- Phellandrene
- Zingiberine
- Cineol and Borneol
- Gingerol
- An Oleoresin-Gingerin

- Resins and starch
- $\beta$ -Sesquiphellandrene
- Gingerdiols, Gingerdiacetates.

*Ref: Indian Herbal Pharmacopoeia*

#### **Articles on *Zingiber officinale*:**

##### ***Zingiber officinale* natural gold:**

It is consumed worldwide as a spice and flavoring agent and is attributed to have many medicinal properties. The British Herbal Compendium reported its action as carminative, anti- emetic, spasmolytic, peripheral circulatory stimulant and anti inflammatory. The oil of ginger is a mixture of constituents, consisting of monoterpenes (phellandrene, camphene, cineole, citral, and borneol) and sesquiterpenes (zingiberene, zingiberol, zingiberenol,  $\beta$ -bisabolene, sesquiphellandrene, and others). Aldehydes and alcohols are also present

**Effect on gastrointestinal tract:** Some active components of ginger are reported to stimulate digestion, absorption, relieve constipation and flatulence by increasing muscular activity in the digestive tract. It is also significantly reduced the nausea and vomiting.

*International Journal of Pharma and Bio Sciences*

[http://ijpbs.net/volume2/issue1/pharma/\\_29.pdf](http://ijpbs.net/volume2/issue1/pharma/_29.pdf)

#### **Overview of pharmacodynamic data regarding the herbal substance(s)/preparation(s) including data on relevant constituents Gastrointestinal motility:**

Gastrointestinal motility of *zingiber officinalis* in a placebo-controlled, double-blind, cross-over study in 12 male volunteers, Micklefield et al. [1999] reported that inter-digestive antral motility of the stomach during phase III of the migrating motor complex and the motor response to a test meal in the corpus measured by stationary manometry were stimulated by ginger (200 mg of ginger rhizome extract) in both the fasting and postprandial states. However, a randomised, placebo-controlled, cross-over study by Phillips et al. [1993] did not observe an impact on gastric emptying rate in 16 healthy volunteers using the oral paracetamol absorption technique (without an accompanying nutrient load) after 1 g (2 capsules) of powdered ginger, suggesting that ginger, although increasing motility, may not affect the gastric emptying rate

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Herbal\\_-HMPC\\_assessment\\_report/2012/06/WC500128140.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-HMPC_assessment_report/2012/06/WC500128140.pdf)

## 2. KADUKUROHINI - கடுகுரோகணி

<b>Botanical Name</b>	:	<i>Picorrhiza scrophulariflora</i>
<b>English Name</b>	:	Black Hellebore
<b>Family</b>	:	Scrophulariaceae
<b>Part used</b>	:	Root

### ORGANOLEPTIC CHARACTER

<b>Suvai</b>	:	Kaippu, karppu
<b>Thanmai</b>	:	Veppam
<b>Pirivu</b>	:	Karppu

பொது குணம் :

கடுகுரோகணி

“மாந்தஞ் சுரமையம் வாயுகரப் பானாமஞ்

சேர்ந்தமலக் கட்டு திரிதோடம் - போந்தபொட்டுப்

புண்வயிறு நோயிவைபோம் பொற்கொடியே – பேதியுண்டாம்

திண்கடுகு ரோகணிக்குத் தேர்”

(அகத்தியர் குணவாகடம்)

### CHEMICAL CONSTITUENTS:

- Iridoid glycosides,
- Picroside I
- Kutkoside

*Ref: Indian Herbal Pharmacopoeia*

### ACTIONS:

- Cathartic
- Antiperiodic
- Anthelmentic

### Articles on *Picorrhiza kurroa*:

#### International journal of pharmaceutical research and biopharmaceutical research

##### Bitter Glycoside of Picorrhiza

In general, bitters are the edible natural products mostly consumed before any normal meals to stimulate as well as enhance the appetite. However, the bitter glycosidase a class do possess almost similar activities like the bitters such as: digestive, stomachic and febrifuge. Therapeutically, the bitters have been found to exert their stimulant effects on the gustatory (i.e. related to the sense of taste) nerves located in the mouth and ultimately give rise to an improved gastric juice secretion in the stomach. The bitter glycosides have been found not confined to the same chemical class, but the most important ones amongst them essentially possess the pyran cyclopentane ring. A number of bitter glycosides isolated from natural plants have been put into actual therapeutic practice, namely: Picorrhiza, Gentian and Chirata

<Http://www.ijprbs.com/issuedocs/2013/8/IJPRBS%20285.pdf>

### 3. **KALI PAKKU** -- களிப்பாக்கு

<b>Botanical Name</b>	:	<i>Areca catechu</i>
<b>English Name</b>	:	Areca nut boiled tender
<b>Family</b>	:	Fabaceae
<b>Part used</b>	:	Seeds

#### ORGANOLEPTIC CHARACTER

<b>Suvai</b>	:	Thuvarpu
<b>Thanma</b>	:	Veppam
<b>Pirivu</b>	:	Karppu

பொது குணம் :

களிப்பாக்கு

“களிப்பாக்குத் தின்றக்காற் கண்டத்துட் கோழை

யொளிப்பாபாகக் கட்டுமி. துண்மை – தளிர்ப்பான

பித்த அரோசகம்போம் பேதிமிக உண்டாகுஞ்

சித்த மகிழ்ச்சியுறுஞ் செப்பு”

(அகத்தியர் குணவாகடம்)

### CHEMICAL CONSTITUENTS:

- Tannins
- Catechin
- Catechu tannic acid
- Flavonoids
- Flavonols-quercitrin
- Quercitin

*Ref: Indian Herbal Pharmacopoeia*

### ACTIONS

- Astringent
- Stimulant

### Articles on *Areca catechu*:

#### ***Areca catechu*: A comprehensive pharmacological Study:**

The main constituents of the areca nut are carbohydrate, fats, fibre, polyphenol including flavonoids and tannins, alkaloids and minerals (IARC, 2004). The fatty acid constituents of the *A. catechu* nut oil are; lauric 19.5, myristic 46.2, palmitic 12.7, stearic 1.6, decanoic 0.3, oleic 6.2, linoleic 5.4, dodecenoic 0.3, tetradecenoic 0.6 and hexadecenoic 7.2%. The chief component glycerides are 56% of fully saturated (trimyristin, dimyristins and lauromyristopalmitin); 30% monounsaturated disaturated (mainly hexadeceno-lauromyristins) and 14% of diunsaturated-monosaturated (oleolinoleo-glycerides, mostly oleolinoleopalmitin).

Areca is used for treatment of a mental disorder called schizophrenia and an eye disorder called glaucoma; it is also as a mild stimulant; and as a digestive aid. Some people used areca as a recreational drug because it speeds up the central nervous system.

<http://www.journalcra.com/article/areca-catechu-comprehensive-pharmacological>

#### 4. SEENTHIL – சிந்தில்

<b>Botanical Name</b>	:	<i>Tinospora cordifolia</i>
<b>English Name</b>	:	Heart leaved moon seed, tinospora, Gulanchatinospora
<b>Family</b>	:	Menispermaceae
<b>part used</b>	:	Stem

#### ORGANOLEPTIC CHARACTER

<b>Suvai</b>	:	Kaippu
<b>Thanmai</b>	:	Veppam
<b>Pirivu</b>	:	Kaarppu

#### CHEMICAL CONSTITUENTS:

- Berberine
- Cordifolioside,
- Asesquiterpene,
- Choline tinosporic acid
- Cordioside

*Ref: Indian Herbal Pharmacopoeia*

#### ACTIONS:

- Stomachic
- Mild diuretic
- Antioxidant
- Antispasmodic

### Articles on *Tinospora cordifolia*:

#### Chemistry and medicinal properties of *Tinospora cordifolia* (guduchi):

The stem of *Tinospora cordifolia* is one of the constituents of several ayurvedic preparations used in general debility, dyspepsia, fever and urinary diseases. The stem is bitter, stomachic, diuretic, stimulates bile secretion, causes constipation, allays thirst, burning sensation, vomiting, enriches the blood and cures jaundice. The extract of its stem is useful in skin diseases. The root and stem of *T. cordifolia* are prescribed in combination with other drugs as an anti-dote to snake bite and scorpion sting. Dry barks of *T. cordifolia* has anti-spasmodic, antipyretic, anti-allergic, anti-inflammatory and anti-leprotic properties.

*Indian Journal of Pharmacology 2003; 35: 83-91 educationaforum*

### 5.KATRALAI-கற்றாழை:

<b>Botanical Name</b>	:	<i>Aloe barbardensis</i>
<b>English Name</b>	:	IndianAloe , Curacao aloe
<b>Family</b>	:	Liliaceae
<b>Part used</b>	:	Pulp ,milk

### ORGANOLEPTIC CHARACTER

<b>Suvai</b>	:	Sirukaippu
<b>Thanmai</b>	:	Thatppam
<b>Pirivu</b>	:	Inipu

### CHEMICAL CONSTITUENTS:

- Glycosides
- Anthracenederivative
- Hydroxyanthraquinonederivatives
- Aloin

*Ref : Indian Herbal Pharmacopoeia*

### ACTIONS:

Purgative



பொது குணம் :

கற்றாழை

“பொல்லாமே கங்கப்படி முச்சூலை குட்டரசம்

அல்லார்மத் தம்பகந்த ரங்குன்மம் எல்லாம்விட்

டேகு மரிக்கு மெரிச்சற் கிரிச்சரமு

மாகு மரிக்கு மருண்டு”

( தேரையர் குணவாகடம்)

## ARTICLES ON *ALOE BARBARDENSIS*:

### Evaluation of the Nutritional and Metabolic Effects of *Aloe vera*

#### Laxative

*Aloe vera* latex is commonly used in the treatment of constipation (de Witte 1993); The laxative effect of the anthraquinone glycosides found in *Aloe vera* latex is well established (Ulbricht et al. 2008). In a double-blind, randomized, controlled trial of 28 healthy adults, aloin was reported to have a laxative effect compared to a placebo that was stronger than the stimulant laxative phenolphthalein (Chapman and Pittelli 1974). In subjects with chronic constipation, a novel preparation containing *Aloe vera*, celandine, and psyllium was found to improve a range of constipation indicators (bowel movement frequency, consistency of stools, and laxative dependence) in a 28-day double-blind trial; however, the effect of *Aloe vera* alone was not investigated in this study (Odes and Madar 1991).

*Herbal Medicine: Biomolecular and Clinical Aspects. 2nd edition*

<http://www.ncbi.nlm.nih.gov/books/NBK92765/>

## 6. KADUKAI- கடுக்காய்

Botanical Name	:	<i>Terminalia chebula</i>
English Name	:	Chebulin myrobalan
Family	:	Combretaceae
Part used	:	Dried matured fruit.

## ORGANOLEPTIC CHARACTER

**Suvai** : Sirukaippu

**Thanmai** : Thatpam

**Pirivu** : Inipu

## CHEMICAL CONSTITUENTS:

- Tannin
- Gallicacid
- Chebulic acid

*Ref: Indian Herbal Pharmacopoeia*

பொது குணம்

கடுக்காய்

“தாடை கழுத்தக்கி தாலு குறியிவிடப்

பீடை சிலிபதமுற் பேதிமுடம் - ஆடையெட்டாத்

தூலமிடி புண்வாத சோணிகா மாலையிரண்

டாலமிடி போம்வரிக்கா யால்”.

(அகத்தியர் குணவாகடம்)

## ACTIONS:

- Laxative
- Purgative
- Alternative

## Articles On Terminalia chebula:

### Haritaki A Boon To Herbalism – A Review

*Terminalia chebula* (Haritaki) is one of the important herbal drug used for treating many diseases including some varieties of cancer. It is rich in chemical constituents. Many pharmacological investigations have been carried out based on its chemical constituents. it contains high phenolic content, especially hydrolyzable tannins, anthraquinone, flavonol, carbohydrates, glucose and sorbitol, chebulic acid, chebulinic acid, ellagic acid, gallic acid, chebulagic acid etc.

*Scholars Academic Journal of Biosciences (SAJB)*

<http://saspublisher.com/wp-content/uploads/2014/03/SAJB-22132-136.pdf>

## Comparative laxative evaluation for andrographis paniculata and Terminalia chebula in experimental animal model

Main objective of this study was the Comparative laxative activity evaluation for A. Paniculata & T. chebula in experimental animal model. Our experiment showed that both the extracts of A. paniculata and T. chebula ability to increase the laxative activity in constipation condition. The Property of the herbal extract was determined by in vivo, its effect on faecal output in rats and The results were shown when compared with standard drug Bisacodyl

[http://www.irjponline.com/admin/php/uploads/1690\\_pdf.pdf](http://www.irjponline.com/admin/php/uploads/1690_pdf.pdf)

### 7. Sivathai - வெண்சிவதை

<b>Botanical Name</b>	:	Operculina Turpethum
<b>English Name</b>	:	Turteth root
<b>Family</b>	:	Convolvulaceae
<b>Parts used</b>	:	Root

### ORGANOLEPTIC CHARACTER

<b>Suvai</b>	:	Kaippu
<b>Thanma</b>	:	veppam
<b>Pirivu</b>	:	Karppu

பொது குணம்

வெண்சிவதை வேர்

“உள்ள மலமும் உதவார்த்த மும்வயிற்றைக்

கொள்ளுபித்த வாதமும்போங் கூளுங்காவ் - பிள்ளைகட்குச்

செப்பு கிரசமும்போந் தேனே யுலகத்துள்

தப்பில் சிவதைக்குத் தான்”

(அகத்தியர் குணவாகடம்)

**CHEMICAL CONSTITUENTS:**

- Turpethin resin 4 to 10%,
- Glucoside,
- Turpethin

*Ref: Indian Herbal Pharmacopoeia*

**ACTIONS:**

- Purgative
- Immuno modulatory
- Anti oxidant

**Articles on *Operculina turpethum*:****Non-opioidergic like mechanism for antinociceptive analgesic and antipyretic activity of ethanolic root extract of operculina turpethum in swiss albino mice**

The root extract of *Operculina turpethum* has been used as an anti inflammatory, purgative, hepato-protective agent and antipyretic.

*International Journal of Pharma and Bio Sciences*

[http://www.ijpbs.net/cms/php/upload/2108\\_pdf.pdf](http://www.ijpbs.net/cms/php/upload/2108_pdf.pdf)

Thus Sivathai having anti-inflammatory and anti pyretic action is helpful in the treatment of Kattu mantham.

## **MATERIALS AND METHODS**

Kattu Mantham is one of the common functional GIT disorder in children. In our NIS OPD, 3-5% of cases are approaching Kuzhandhai Maruthuvam department daily with the Symptoms of Kattu Mantham . Hence it was proposed to study about the disease. A Protocol was prepared and submitted before IEC of National Institute of Siddha .The IEC approval was obtained No:NIS/IEC/18-14/20-18-26-08-2014. The trial was registred in Clinical trial Registry of India with Reg .No.CTRI/2016/04/006818 .After obtaining approval from the committee, the clinical study on Kattu mantham ( Dyspepsia ) in children with drug Seenthil kudineer and carried out as per the protocol.

In vitro Carminative activity were conducted in Satya bama university,Chennai and physico chemical activity studies of Seenthil kudineer were done at CRI, Arumbakkam.

After finishing the In vitro Carminative activity studies, 40 cases were selected from the OPD & IPD of Kuzhandhai Maruthuvam Department, National Institute of Siddha. They were treated with the trial drug with Seenthilkudineer and observed for prognosis clinically.

### **PREPARATION OF SEENTHIL KUDINEER:**

#### **COLLECTION OF RAW DRUGS**

The required drugs were purchased from a reputed raw drug shop at kanda swamy kovil street paris .

#### **AUTHENTICATION**

Raw drugs were authenticated by the Medicinal Botanist in National Institute of Siddha, Chennai. The test drug Seenthil kudineer was prepared at Gunapadam lab, National Institute of Siddha.Chennai-47

#### **.Purification Method:**

- Chukku - To soak in chunnambu thelineer for 3 hours dried and to peel off outer skin
- Seenthil - To peel off the outer skin.
- Sivathai - To remove veins, boil in milk, dried it in sunlight

- Kadugurookini - To soak in neem leaves juice for three hours and dried it in sunlight.
- Kadukai - To remove inner seeds.
- Kalipakku - soak in water and dried in sunlight
- Katralai sarugu - remove thorns and dried it in sunlight

Sikicha Rathina Deepam

### **Preparation of the Seenthil kudineer:**

#### **Ingredients:**

Tinospora cordifolia (seenthil thandu)	- 4 grams
Araca catechu (kali pakku)	- 4 grams
Operculina terpeethum (sivathai)	- 4 grams
Terminalia chebula (kadukkai)	- 4 grams
Zingiber officinalis (sukku)	- 4 grams
Picrorhiza scrophulariflora (kadukurokini)	- 4 grams
Aloe barbadence (katralai sarugu)	- 4 grams

*Ref : Balavagadam(pg 93)*

#### **Method of preparation:**

Above mentioned drugs were purified by purification method mentioned below . All purified drugs are coarsely powdered and kept in a clean glass container .

#### **Method of preparing Kudineer:**

Above mentioned decoction powder ( 26 gms) was taken and mixed with 80 ml of water and boiled until one eighth of decoction.

**Dosage :** 10 ml b.i.d

**Drug Storage:**

Prepared medicine in coarse powder form will be stored in clean and dry container.

**Dispensing:**

Prepared medicine of 52 gms will be given as coarse powder form in separate air lock covers.

**PHYSICO CHEMICAL ANALYSIS**

The physicochemical analysis of the test drug Seenthil kudineer was carried out as per WHO guidelines (Anonymous 1998). The test procedures were done at Siddha Central Research Institute (CRI), Arumbakkam Chennai. Since the form of the drug is in powder the parameters such as Loss on Drying at 105°C, Total ash, Acid insoluble ash Water soluble Extractive, Alcohol Soluble Extrative, pH was done using Quality control methods for medicinal plants materials.

**Loss on drying of the sample at 105°C**

4g of test drug was weighed in a previously weighed 100ml beaker and heated in an oven at 105°C for 5 hours. Cooled in a dessicator and weighed. Repeated the procedure till constant weight was obtained. The percentage loss in weight of the test drug was calculated by the following formula.

**Calculation:**

$$\text{Percentage of loss on drying at } 105^{\circ}\text{C} = \frac{\text{Loss in weight of test drug}}{\text{Weight of test drug taken}} \times 100$$

**Ash content**

**a. Total ash content**

4g of test drug was weighed accurately in a previously ignited and tared silica dish. The material was evenly spread and ignited in a muffle furnace at 600°C until it became white indicating the absence of carbon. The dish was cooled in a dessicator and weighed. As carbon free ash cannot be obtained in this manner, the dish was cooled and the residue

moistened with sufficient quantity of water. Dried on a water bath and then ignited in the electric furnace to get the constant weight. Cooled the dish in a dessicator and then weighed. The percentage of total ash of air-dried materials was calculated as per the formula given below.

**Calculation:**

$$\text{Percentage of total ash} = \frac{\text{Weight of the ash}}{\text{Weight of test drug taken}} \times 100$$

**b. Acid-insoluble ash**

The total ash of the test drug was found out as described above. To the dish containing the total ash was added 45 ml of 1: 5 hydrochloric acid in three portions of 13 ml each time. Boiled gently for 5 minutes and filtered. Collected the insoluble matter on an ashless filter paper (Whatman No.41) and washed with distilled water until the residue was free from acid. Transferred the filter paper containing the insoluble mater to the original dish. Dried and ignited to the constant weight. Cooled the dish in a dessicator, and then weighed. Calculated the percentage of acid-insoluble of the air-dried material by the given following formula.

**Calculation:**

$$\text{Percentage of acid-insoluble ash} = \frac{\text{Weight of the acid-insoluble residue}}{\text{Weight of test drug taken}} \times 100$$

**Extractive of the test drug**

**a. Water-soluble extractive of the test drug**

4 g of the test drug was weighed accurately in a glass stoppered flask. Added 100 ml of distilled water and shaken occasionally for 6 hours and then allowed to stand for 18 hours. Filtered rapidly taking care not to lose any solvent and pipetted out 25 ml of the filtrate in a preweighed 100 ml beaker and evaporated to dryness on a water bath. Kept in an air oven at 105°C for 6 hours. Cooled in a dessicator and weighed. Repeated the experiment twice, and taken the average value. The percentage of water soluble extractive was calculated by the formula given below.



**Calculation:**

$$\text{Percentage of water soluble extract} = \frac{\text{Weight of the extract}}{\text{Weight of sample taken}} \times \frac{100}{25} \times 100$$

**b. Alcohol-soluble extractive of the sample**

4 g of the sample was weighed accurately in a glass stoppered flask. Added 100 ml of distilled alcohol (approximately 95%) and shaken occasionally for 6 hours and then allowed to stand for 18 hours. Filtered rapidly taking care not to lose any solvent and pipetted out 25 ml of the filtrate in a preweighed 100 ml beaker and evaporated to dryness on a water bath.

Kept in an air oven at 105°C for 6 hours and cooled in a dessicator and weighed. Repeated the experiment twice, and taken the average value. The percentage of alcohol soluble extractive was calculated by the formula given below.

**Calculation:**

$$\text{Percentage of alcohol soluble extract} = \frac{\text{Weight of the extract}}{\text{Weight of sample taken}} \times \frac{100}{25} \times 100$$

**i. Determination of pH**

The pH of the Seenthil kudineer was estimated as per the method prescribed in the Indian standard (IS) -6940(1982). The procedure was done at NIS, Chennai 47.

One gram of the testdrug was taken into a 100ml graduated cylinder containing about 50 ml of water. The cylinder was shaken vigorously for two minutes and the suspension was allowed to settle for hour at 25°C to 27°C, then 25 ml of the clear aqueous solution was transfered in to a 50 ml beaker and tested for pH using digital pH meter .

### 5.1.2 Pharmacological activity

#### In-vitro Carminative Activity

Project ID : PSA/30/16-17

Institute : National Institute of Siddha, Chennai, Tamil Nadu, India

Sample Name : SeenthilKudineer

Sample ID : SK

#### **Preparation of Seenthil Kudineer Decoction**

Decoction of the raw sample was prepared by extracting the crude drug with distilled water by using soxhlet extraction setup. The decoction thus collected will be used for the following estimation



#### **In-vitro Carminative activity acid-base titration technique**

In-vitro carminative activity of the SeenthilKudineer was evaluated by modified method of Swapnil Sharma et al. About 5, 10, 20 and 40 ml of the SK decoction were placed in conical flask fitted with air-tight nozzle, to this 100 ml of distill water was added.

About 100 ml of NaOH {1M, previously standardized to oxalic acid} was poured into a plastic container fitted with aeration tubing system that was connected directly to the

reaction vessel containing varying volume of test sample (SK). The flask was agitated manually for the next 45 mins and was allowed to stand for overnight. The carbon dioxide gas evolved from the reaction vessel was allowed to pass into a plastic container containing excess sodium hydroxide where it was absorbed and converted into equivalent amount of sodium carbonate. The resulting mixture consisting of excess sodium hydroxide and sodium carbonate was titrated with standard HCl using phenolphthalein as indicator to get first endpoint and in continuation to this the second endpoint was enumerated using methyl orange as indicator. The difference in milliliters between the first & second endpoints was used to calculate the carbon dioxide content per gram of sample.

Vol. of titrant x molarity of std. acid x mol. Wt. of CO<sub>2</sub> = mass of CO<sub>2</sub> in gm

Molarity of the Acid is 0.0829M

Mol. Wt. of CO<sub>2</sub> is 44.01 g/mol

Triplicate 1

Volume of Test Sample	Difference in Titration value (ml)	Mass of CO <sub>2</sub> in gm
5	1.8	6.56
10	2.4	8.75
20	3.6	13.13
40	4.6	16.78

Triplicate 2

Volume of Test Sample	Difference in Titration value (ml)	Mass of CO <sub>2</sub> in gm
5	2	7.29
10	2.2	8.02
20	3.3	12.03
40	4.5	16.41

Triplicate 3

Volume of Test Sample	Difference in Titration value (ml)	Mass of CO <sub>2</sub> in gm
5	1.7	6.20
10	2.4	8.75
20	3.4	12.40
40	4.2	15.32

## Reaction Setup



## Evolution of Carbon dioxide from the reaction mixture



### **5.1.3 Biochemical analysis**

Biochemical Analysis of Seenthil kudineer was done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate.

#### **Preparation of Extract:**

5ml of sample was taken in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical constituents in it.

### **5.1.3 Biochemical analysis**

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#### **Procedure:**

##### **Test for Silicate**

A 2ml of the sample was shaken well with distilled water.

##### **Action of Heat:**

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.

##### **Action of Heat:**

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.

**Ash Test:**

A filter paper was soaked into a mixture of extract and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited

**I. Test for Acid Radicals****Test for Sulphate:**

2ml of the above prepared extract was taken in a test tube to this added 2ml of 4% dil ammonium oxalate solution

**Test for chloride:**

2ml of the above prepared extracts was added with 2ml of dil.HCl is added until the effervescence ceases off.

**Test for Phosphate:**

2ml of the extract were treated with 2ml of dil.ammonium molybdate solution and 2ml of con.HNO<sub>3</sub>.

**Test for carbonate:**

2ml of the extract was treated with 2ml of dil. magnesium sulphate solution.

**Test for Nitrate:**

1gm of the extract was heated with copper turning and concentrated H<sub>2</sub>SO<sub>4</sub> and viewed the test tube vertically down.

**II. Test for Basic radicals****Test for lead:**

2ml of the extract was added with 2ml of dil.potassium iodine solution.

**Test for copper:**

One pinch (25mg) of extract was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.

**Test for Aluminium:**

To the 2ml of extract dil.sodium hydroxide was added in 5 drops to excess.

**Test for Iron:**

- a. To the 2ml of extract add 2ml of dil.ammonium solution
- b. To the 2ml of extract 2ml of thiocyanate solution and 2ml of con HNO<sub>3</sub> is added.

**Test for Zinc:**

To 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.

**Test for Calcium:**

To 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution

**Test for Magnesium:**

To 2ml of extract dil.sodium hydroxide solution was added in drops to excess.

**Test for Ammonium:**

To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.

**Test for Potassium:**

A pinch (25mg) of extract was treated of with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.

**Test for Sodium:**

2 pinches (50mg) of the extract is made into paste by using HCl and introduced into the blue flame of Bunsen burner.

**Test for Mercury:**

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.

**Test for Arsenic:**

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution

**III. Miscellaneous****Test for Starch:**

2ml of extract was treated with weak dil.Iodine solution.

**Test For Reducing Sugar:**

5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.

**Test for the Alkaloids:**

- a) 2ml of the extract was treated with 2ml of dil.potassium Iodide solution.
- b) 2ml of the extract was treated with 2ml of dil.picric acid.
- c) 2ml of the extract was treated with 2ml of dil.phosphotungstic acid.

**Test for Tannic Acid:**

2ml of extract was treated with 2ml of dil.ferric chloride solution.

**Test for Unsaturated Compound:**

To the 2ml of extract 2ml of dil.Potassium permanganate solution was added.

**Test for AminoAcid:**

2 drops of the extract was placed on a filter paper and dried well. 20ml of Burette reagent is added.

**Test for Type of Compound:**

2ml of the extract was treated with 2 ml of dil.ferric chloride solution.



## **5.2 CLINICAL STUDIES:**

### **Population and Sample:**

The population consists of paediatric patients attending the OPD of AyothidossPandithar Hospital, National Institute of Siddha, Chennai-47.

The sample consists of 1-3 years age group fulfilling any 3 of the inclusion criteria and none of the exclusion criteria.

**Sample size:** 40 Patients

**Study place:** OPD &IPD of AyothidossPandithar hospital,  
National Institute of Siddha,  
Tambaram sanatorium,  
Chennai – 46.

### **Inclusion criteria:**

Age 1 to 3 years

Sex: Both male and female children.

Children with minimum 3 clinical symptoms such as

1. Indigestion
2. Stomach pain
3. Cough
4. Fever
5. Yawning
6. Perspiration
7. Constipation

### **Exclusion criteria:**

1. Irritable Bowel Syndrome
2. Childhood Asthma
3. High temp >102°F
4. Severe cough
5. Intolerable stomach pain

**Withdrawal criteria:**

1. Occurrence of any adverse effect
2. Poor patient compliance & defaulters.
3. Patient turned unwilling to continue in the course of clinical trial.
4. Exacerbation of symptoms

**Study design** : An Open clinical trial.

**Study duration** : 12 Months

**Dosage of drugs** : 10ml (bid)

**Name of the trial drug** : Seenthil kudineer

**A.CLINICAL ASSESSMENT**

Clinical assessment were done with reduction of following symptoms

- Indigestion
- Stomach pain
- Cough
- Fever
- Constipation

**B.SIDDHA METHOD OF ASSESSMENT**

- Nilam
- Kaalam
- Uyirathukkal
- Udalthaathukkal
- Envagaithervugal

**Study Enrollment:**

1. In this study, patients reporting at the NIS OPD with the three or more clinical symptoms will be examined clinically for enrolling in this study based on the inclusion and exclusion criteria.
2. The patients who are to be enrolled would be informed (Form VI) about the study, experimental medicine, possible outcomes and the objectives of the study in the language and terms understandable to them and to their informants.

3. After ascertaining the patient and informant willingness, informed consent would be obtained in writing from them in the consent form (Form II).
4. All these patients will be given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phonenumber etc. will be given, so as to report easily communication for the sake of the patient.
5. Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Proforma in the history and clinical assessment forms (form IV) separately. Screening Form- I will be filled up; Form III will be used for recording the patients' history, clinical examination of symptoms and signs respectively.
6. Patient would be advised to take the trial drug and appropriate dietary advice (Form X) would be given according to the patients' perfect understanding.

#### **Conduct of the Study:**

The trial drug "*SeenthilKudineer*" is given for 1 day. For OP patients before and after treatment the clinical assessment will be done and prognosis is noted on 3<sup>rd</sup> day. For IP patients the drug is provided and prognosis is noted and clinical assessment will be done on 1<sup>st</sup> day itself.

#### **Data Managment:**

After enrolling the patient in the study, a separate file for each patient will be opened and all forms will be filed in the file. When study patient visits OPD during the study period, the respective patient file will be taken and necessary recordings will be made at the assessment form or other suitable form. The screening forms will be filed separately.

The Data recordings will be monitored for completion and adverse event by HOD and data logical recording and completeness will be monitored by statistician (Sr. Research Officer (Statistics)). All forms will be further scrutinized in presence of Investigator by Sr. Research Officer (Statistics) for logical errors and incompleteness of data before entering onto computer to avoid any bias. No modification in the results is permitted for unbiased report.

Any missed data found in during the study, it will be collected from the patient, but the time related data will not be recorded retrospectively All collected data will be entered using MS access software onto computer. Investigator will be trained to enter the patient data and cross checked by SRO.

#### **Adverse Effect/Serious Effect Management:**

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National institute of siddha and the same will be reported to regional pharmacovigilance center.

#### **Ethical Issues:**

1. No other external or internal medicines will be used.
2. The data collected from the patient's informant will be recorded. The patient's informant will be informed about the diagnosis, treatment and follow-up.
3. After the consent of the patient's informant (through consent form), patient will be enrolled in the study.
4. Informed consent will be obtained from the patient's informant explaining in the understandable language to the patient's informant.
5. Treatment would be provided free of cost.
6. In conditions of treatment failure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care.

#### **Data Collection Forms:-**

Form I	Screening & Selection Proforma
Form II	Consent Form
Form III	History Proforma
Form IV	Assessment Form
Form V	Drug compliance
Form VI	Patient information sheet
Form VII	Withdrawal
Form VIII	Adverse reaction
Form IX	Pharmaco vigilance
Form X	Dietary form

## 6. RESULTS AND OBSERVATIONS

### Preclinical studies:

#### Physicochemical analysis of Seenthil kudineer

S.No.	Parameters	Results
1	Loss on Drying at 105°C	10.27%
2	Total Ash	4.92%
3	Acid insoluble Ash	0.53%
4	Water soluble Extractive	20.55%
5	Alcohol Soluble Extractive	15.20%
6	pH	4.70

#### Biochemical analysis of Seenthil Kudineer

##### Results of Acid radicals studies

S.NO	Parameter	Observation	Result
1	Test for Sulphate	Cloudy appearance Present	Positive
2	Test for Chloride	-	Negative
3	Test For Phosphate	-	Negative
4	Test For Carbonate	-	Negative
5	Test For Nitrate	-	Negative
6	Test for Sulphide	-	Negative
7	Test For Fluoride & oxalate	-	Negative
8	Test For Nitrite	-	Negative
9	Test For Borax	-	Negative

#### Interpretation

The acidic radicals test shows the presence of **Sulphate**.

**Results of basic radicals studies:**

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Negative
2	Test for Copper	-	Negative
3	Test For Aluminium	Brown precipitate is formed	Positive
4	Test For Iron	-	Negative
5	Test For Zinc	White precipitate is formed	Positive
6	Test for Calcium	Cloudy appearance and white precipitate present	Positive
7	Test For Magnesium	White precipitate obtained	Positive
8	Test For Ammonium	-	Negative
9	Test For Potassium	-	Negative
10	Test For Sodium	-	Negative
11	Test For Mercury	-	Negative
12	Test For Arsenic	-	Negative

**Interpretation**

The basic radical test shows the presence of **calcium, Aluminium, Zinc, Magnesium**, and absence of heavy metals such as lead, Iron, arsenic and mercury.

**Miscellaneous:**

S.NO	Parameter	Observation	Result
1	Test for Starch	-	Negative
2	Test for Reducing sugars	-	Negative
3	Test For Alkaloids	Yellow colour developed	Positive
4	Test For Tannic acid	Blue-black precipitate obtained	Positive
5	Test for unsaturated compounds	-	Negative
6	Test for Amino acid	-	Negative
7	Test For Type of compounds	Blue colour developed	Phenol cresol and hydroquinone are present

**Interpretation**

The Miscellaneous test shows the presence of **Alkaloids, Tannic acid, Phenol cresol and hydroquinone**

**In-vitro carminative Activity****Result Analysis**

The carminative profiling of the test sample SeenthilKudineer was evaluated on basis of the amount of cabondioxide evolved from the reaction mixture with varying volume of SK. The amount of cabondioxide {g} produced by the 5ml of the sample SK was found to be  $(6.68 \pm 0.55)$ , for 10 ml of sample it was  $(8.51 \pm 0.42)$ , 20 ml of sample it was  $(12.53 \pm 0.53)$  and 40 ml of sample it was  $(16.17 \pm 0.75)$ .

Volume of Test Sample	Difference in Titration value (ml)	Mass of CO <sub>2</sub> in gm
5	1.8	6.689 ± 0.55
10	2.3	8.513 ± 0.42
20	3.4	12.53 ± 0.53
40	4.4	16.17±0.75

Each value represents the mean ± SD. N=3

### Clinical Studies

40 Patients with confirmed diagnosis of with satisfying the inclusion criteria were enrolled after obtaining written informed consent and were to receive *Seenthil kudineer* with dosage of 10 ml bid for 1 day

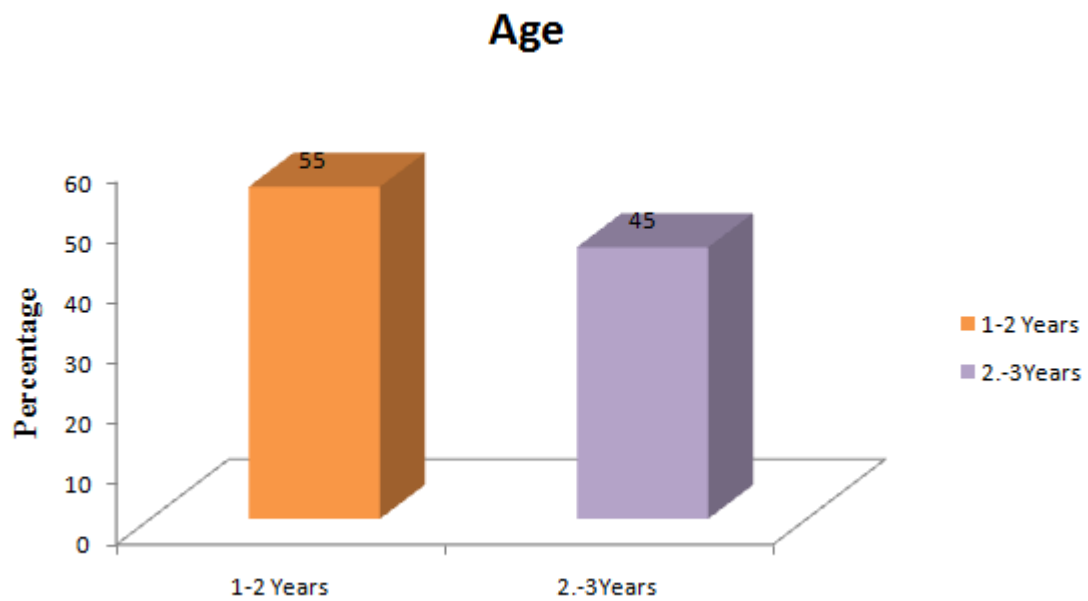
### Results were observed with respect to the following criteria:

1. Age
2. Sex
3. Parent's Socio Economic Status
4. Diet
5. Nilam
6. Paruvakaalam
7. Uyirthatthukkal
8. Ezhuudalkattugal
9. Envagaithervugal
10. Neikuri
11. Clinical features



**Table1. Distributions of patients with Kattu Mantham according to Age**

S.NO	AGE	NO.OF.CASES	PERCENTAGE%
1.	1-2 Years	22	55
2.	2.-3Years	18	45

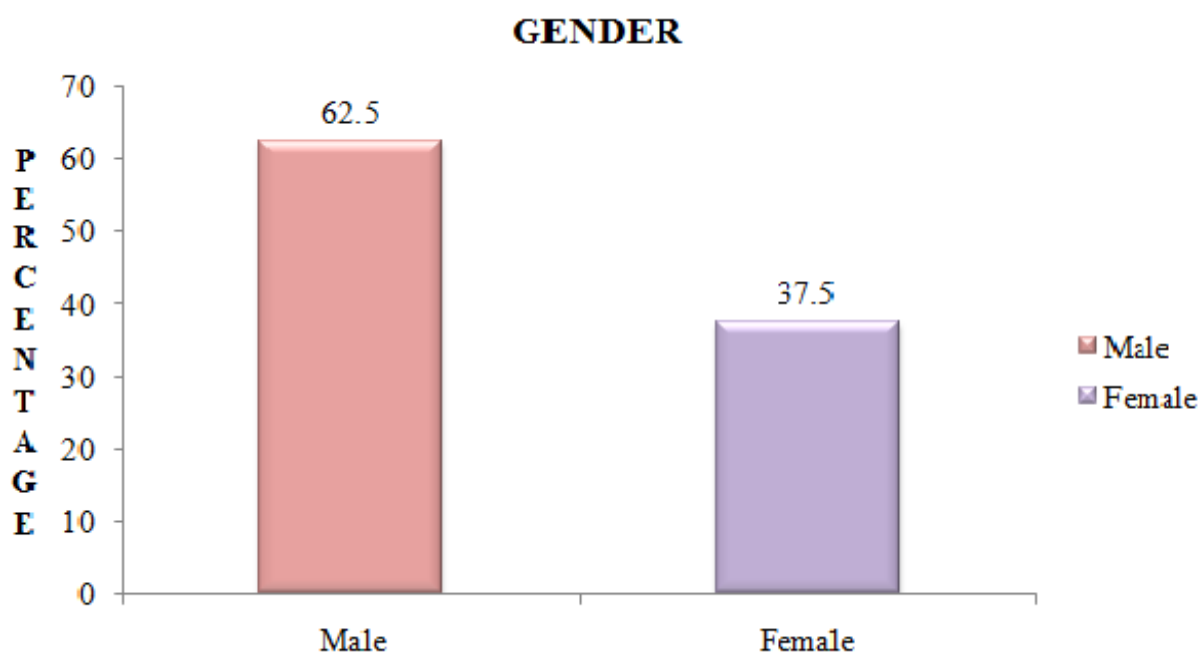


**Inference:**

Out of 40 patients, 55 % of cases were within 1-2years, 45 % of cases were within 2-3 years. (Table1)

**Table 2.Distributions of patients with Kattu mantham according to Gender**

S.No	Sex	No of Cases	Percentage%
1.	Male Child	25	62.5
2.	Female Child	15	37.5

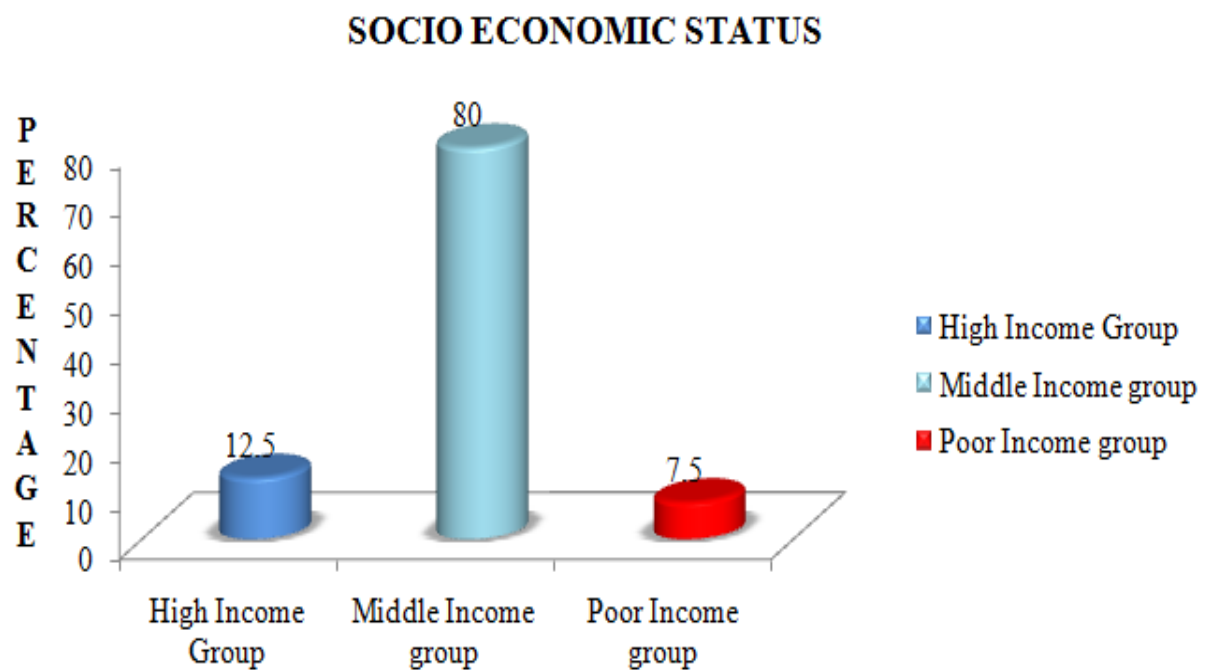


**Inference:**

Out of 40 patients 62.5% were male children and 37.5% were female children. (Table 2)

**Table.3. Distribution of patients with Kattu mantham according to socio-economic status**

S.No	Socio-economic Status	No of Cases	Percentage%
1.	High Income group	5	12.5
2.	Middle Income group	32	80
3.	Poor Income group	3	7.5

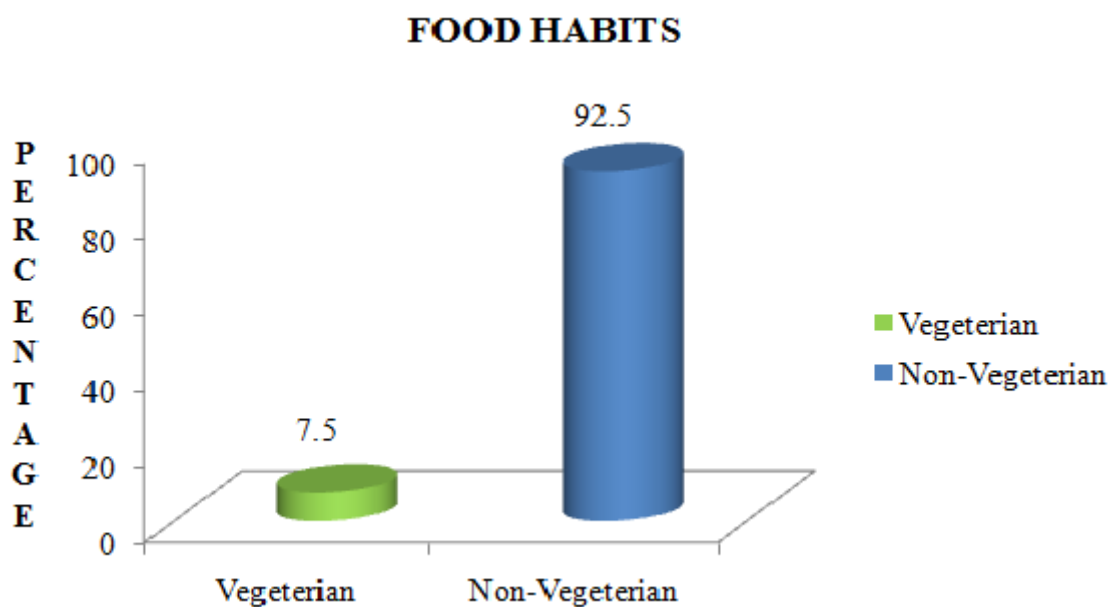


**Inference:**

About 7.5 % patients were under lower income group, 80% patients were under middle income group and 12.5% patients were under high income group. The highest incidence occurred in middle income group.(Table 3).

**Table 4. Distribution of patients with Kattu mantham according to Diet reference**

S.NO	FOOD HABITS	NO OF CASES	PERCENTAGE%
1.	Vegeterian	3	7.5
2.	Non-Vegeterian	37	92.5

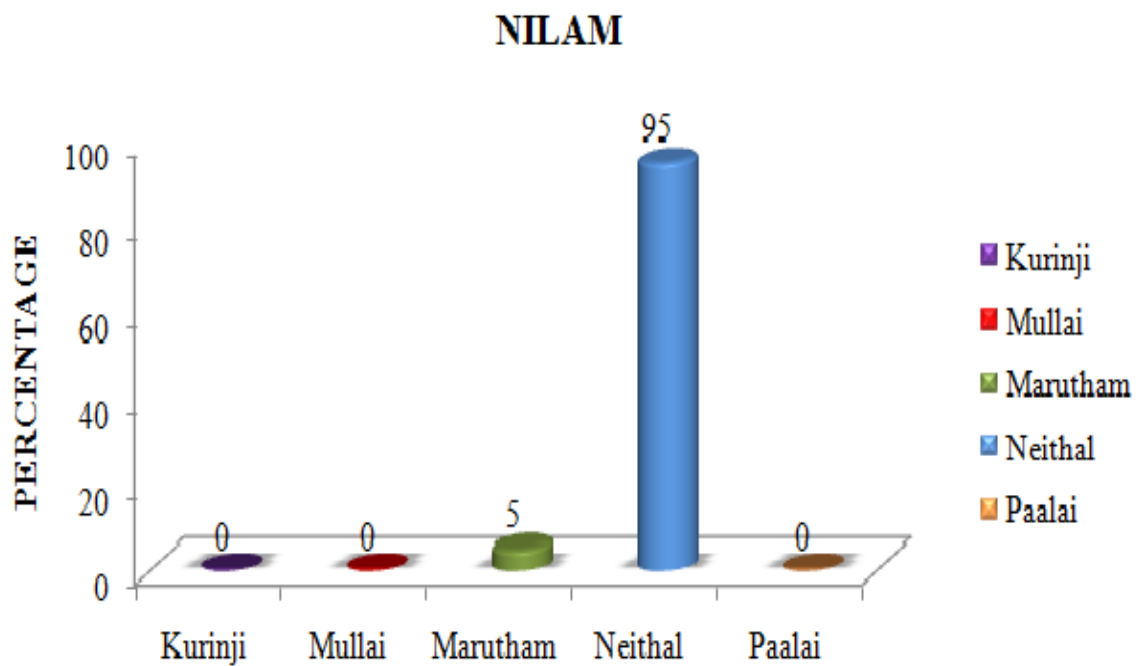


**Inference:**

According to diet, Vegeterian 7.5%, Mixed 92.5% were noted. (Table 4)

**Table.5. Distribution of patients with Kattu mantham according to Nilam**

Nilam	No of cases	Percentage%
Kurinji	0	0
Mullai	0	0
Marutham	2	5
Neithal	38	95
Paalai	0	0

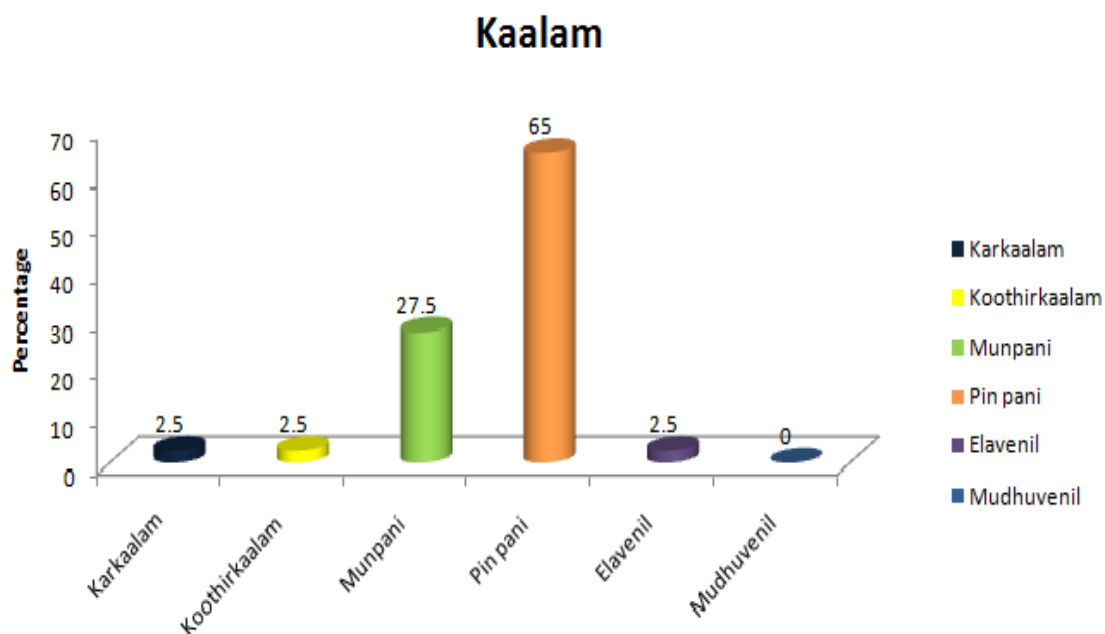


**Inference:**

Among 40 patients, 95 % were from Neithal land, 5 % from Marutham land, 0 % from Mullai land, and 0% from Kurinji land. (Table 5)

**Table.6. Distribution of patients with Kattu mantham according to Paruvakalam**

S.No	Paruvakaalam	No. of cases	Percentage
1.	Karkaalam (Avani – puratasi)	1	2.5
2.	Koothirkaalam (Iyppasi – karthikai)	1	2.5
3.	Munpani (Markazhi – Thai)	11	27.5
4.	Pin pani (Masi – Panguni)	26	65
5.	Elavenil (Chitirai, Vaigasi)	1	2.5
6.	Mudhuvenil (Aani, Aadi)	0	0

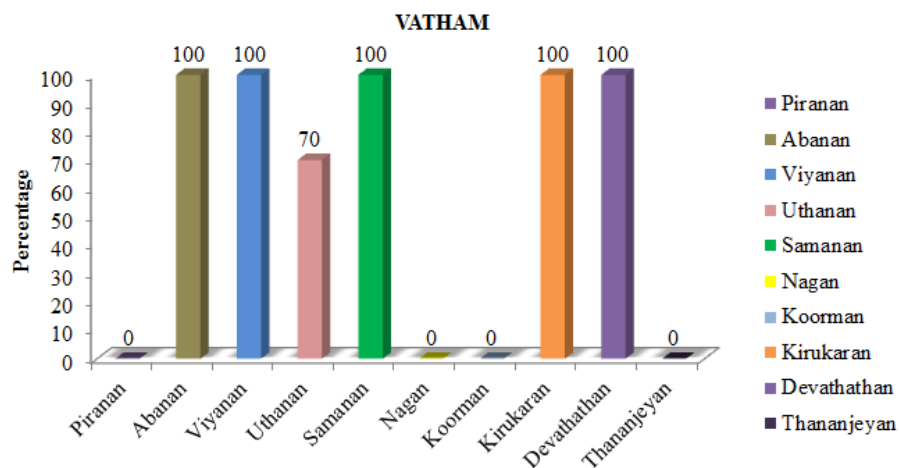


**Inference:**

According to paruva kaalam, high incidence of cases 65% were reported in Pinpanikalam ,27.5% cases were reported in Mun pani kalam, 2.5% cases were reported in elavenil kaalam and 2.5% were from Karkalam,2.5% from karkalam and 2.5% from koothirkalam .(Table 6)

**Table7a. Distribution of patients with Kattu mantham according to derangement of Vatham**

SNO	VATHAM	NO OF CASES	PERCENTAGE%
1.	Piranan	0	0
2.	Abanan	40	100
3.	Viyanan	40	100
4.	Uthanan	28	70
5.	Samanan	40	100
6.	Nagan	0	0
7.	Koorman	0	0
8.	Kirukaran	40	100
9.	Devathathan	40	100
10.	Thananjeyan	0	0

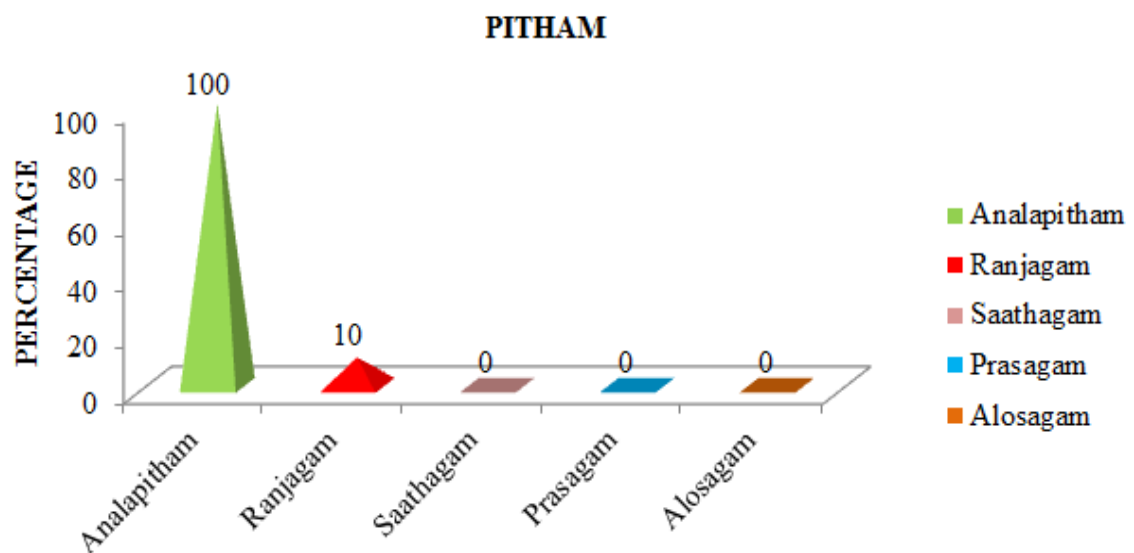


### **Inference:**

According to vatham, derangement of Pranan was 0%, Abanan was 100%, Viyanan was 100% ,Udhanan was 70% samaanam was affected 100 % and Kirukaran was deranged in 100% and devathathan was 100% (Table 7a).

**Table 7b. Distribution of patients with Kattumantham according to derangement of Pitham**

S.No	Types of pitham	No.of Cases	Percentage
1.	Analapitham	40	100
2.	Ranjagam	4	10
3.	Saathagam	0	0
4.	Prasagam	0	0
5.	Alosagam	0	0



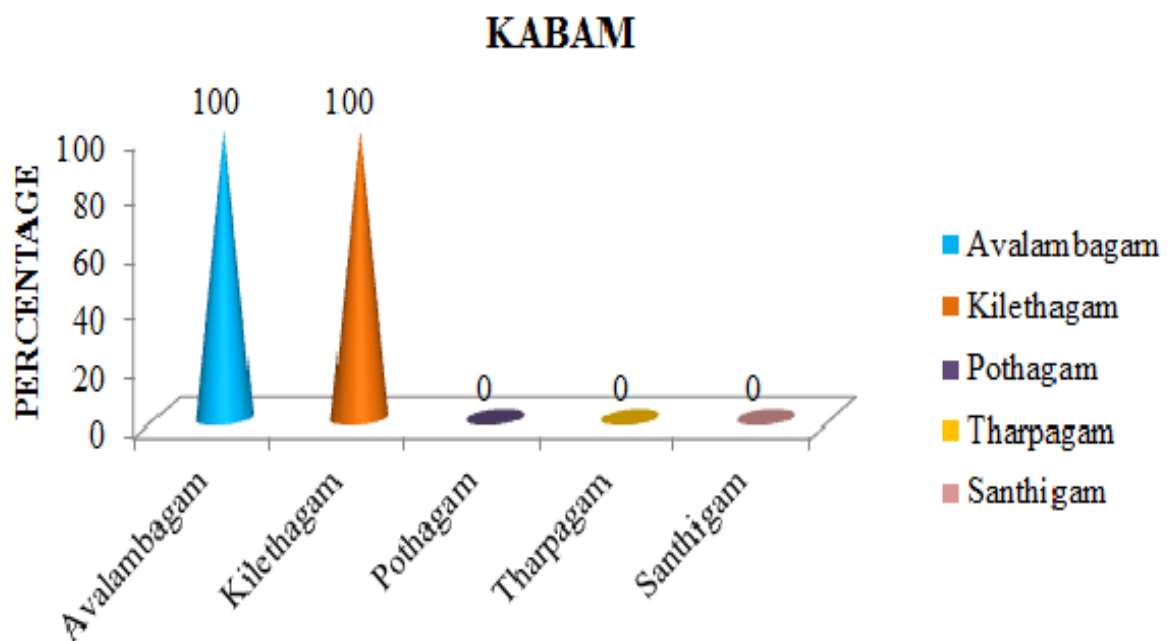
**Inference:**

According to Pitham, derangement of Analapitham was 100% and Ranjagam was 10% (Table 7b).



**Table7c. Distribution of patients with kattu mantham according to dearrangement of Kabam**

S.No	Types of Kabham	No.of Cases	Percentage
1.	Avalambagam	40	100
2.	Kilethagam	40	100
3.	Pothagam	0	0
4.	Tharpagam	0	0
5.	Santhigam	0	0

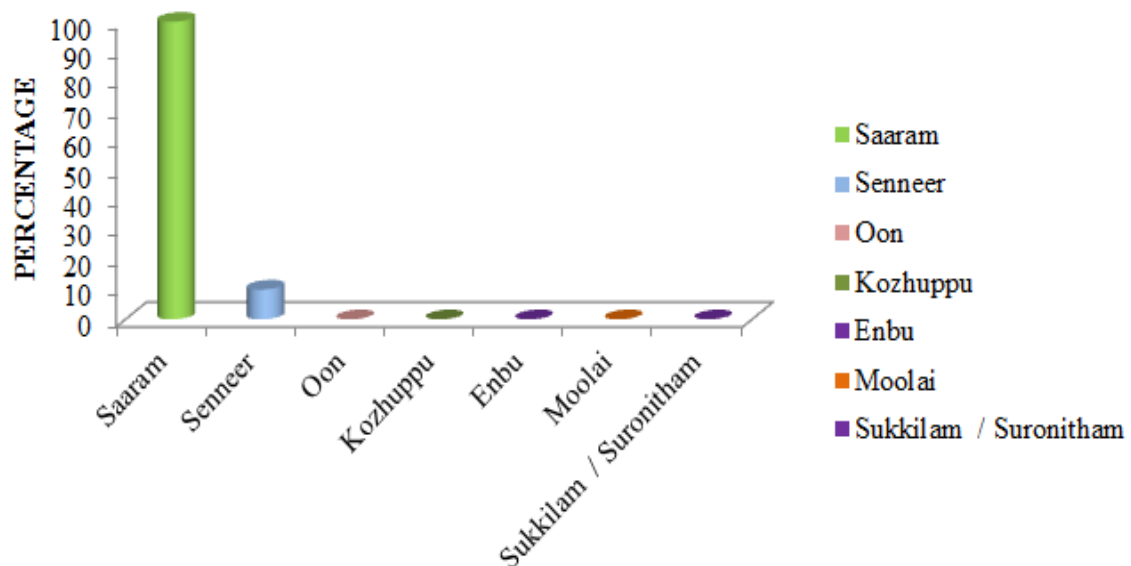


**Inference:** According to Kabam, derangement of Avalambagam was deranged in 100% of cases and Kilethagam was affected in 100% cases (Table7c).

**Table8. Distribution of patients with Kattu mantham according to derangement of Ezhu Udarkattugal**

S.No	Udarkattugal	No.of Cases	Percentage
1.	Saaram	40	100
2.	Senneer	4	10
3.	Oon	0	0
4.	Kozhuppu	0	0
5.	Enbu	0	0
6.	Moolai	0	0
7.	Sukkilam / Suronitham	0	0

### **EZHU UDARKATTUKAL**

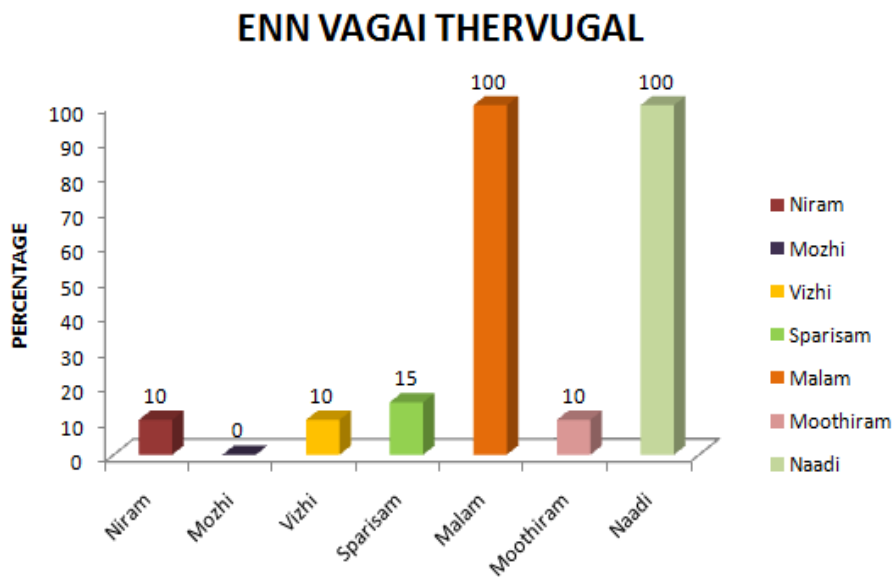


### **Inference:**

Saram was affected in 100% of cases and Seneer was affected 10% (Table 8).

**Table9. Distribution of patients with Kattu mantham according to derangement of Enn vagai thervugal**

S.No	Enn Vagai Thervugal	Percentage%
1	Naa	10
2	Niram	10
3	Mozhi	0
4	Vizhi	10
5	Sparisam	15
6	Malam	100
7	Moothiram	10
8	Naadi	100



**Inference:**

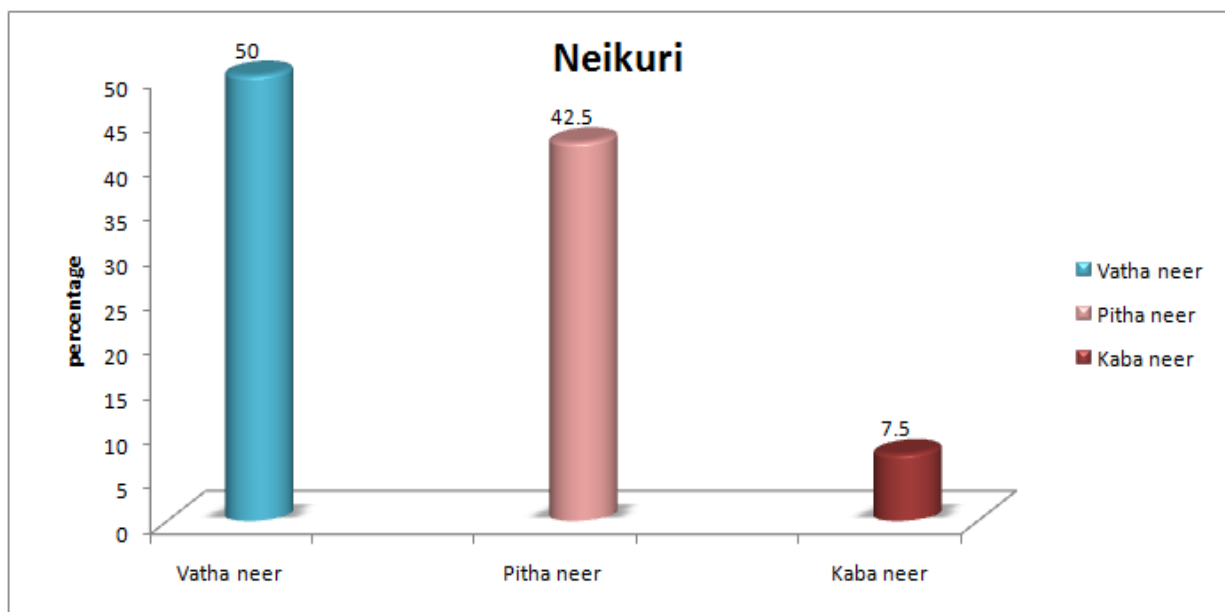
Out of 40 cases Malam was affected in 100% of cases, Sparisam was affected in 15% of cases, Naa and Vizhi was affected in 10% of the cases. (Table 9).

**Inference (Naadi):**

In Naadi, Vathapitham was observed in 50 % of cases, Pithavatham was observed in 50 % of cases

**Table10. Distribution of patients with Kattu mantham according to observation of Neikuri analysis**

S.No	Character of urine	Neikuri Reference	No.of Cases	Percentage
1.	Spreads like snake	Vatha Neer	20	50
2.	Spreads like ring	Pitha Neer	17	42.5
3.	Static as pearl	Kaba Neer	3	7.5

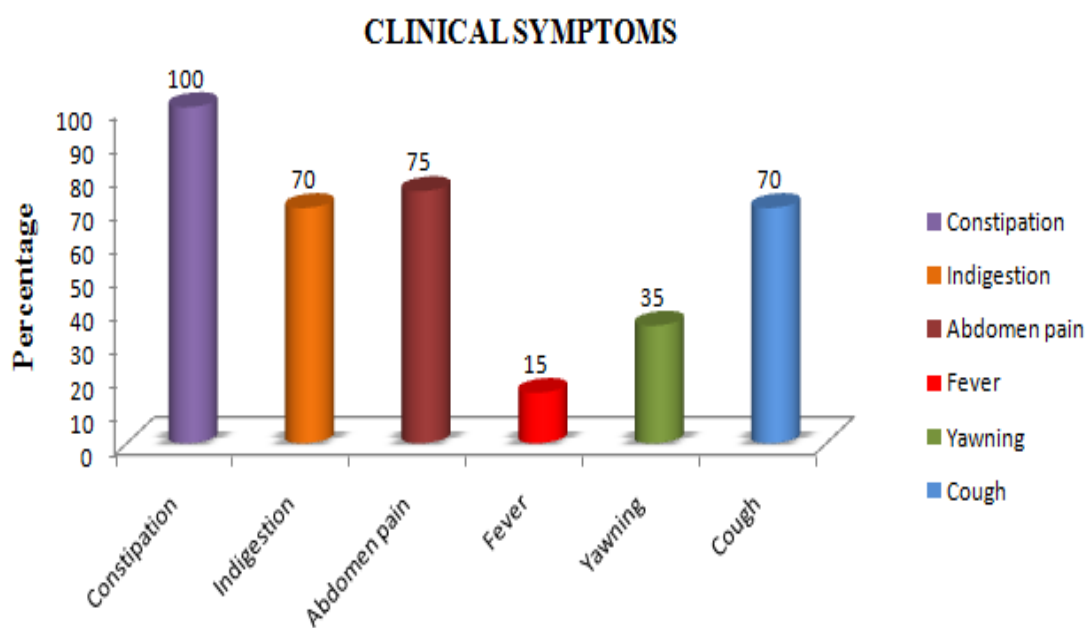


### Inference

According to Neikuri, Vatha neer was observed in 50 % of cases, pitha neer was observed in 42.5 % of cases, Kaba neer was observed in 7.5 % of cases.(Table 10)

**Table – 15 Distribution of clinical symptoms of Kattu mantham**

S.No	Signs and Symptoms	No.of cases (out of 40)	Percentage
1	Constipation	40	100
2	Indigestion	28	70
3	Abdomen pain	30	75
4	Fever	6	15
5	Yawning	14	35
6	Cough	28	70



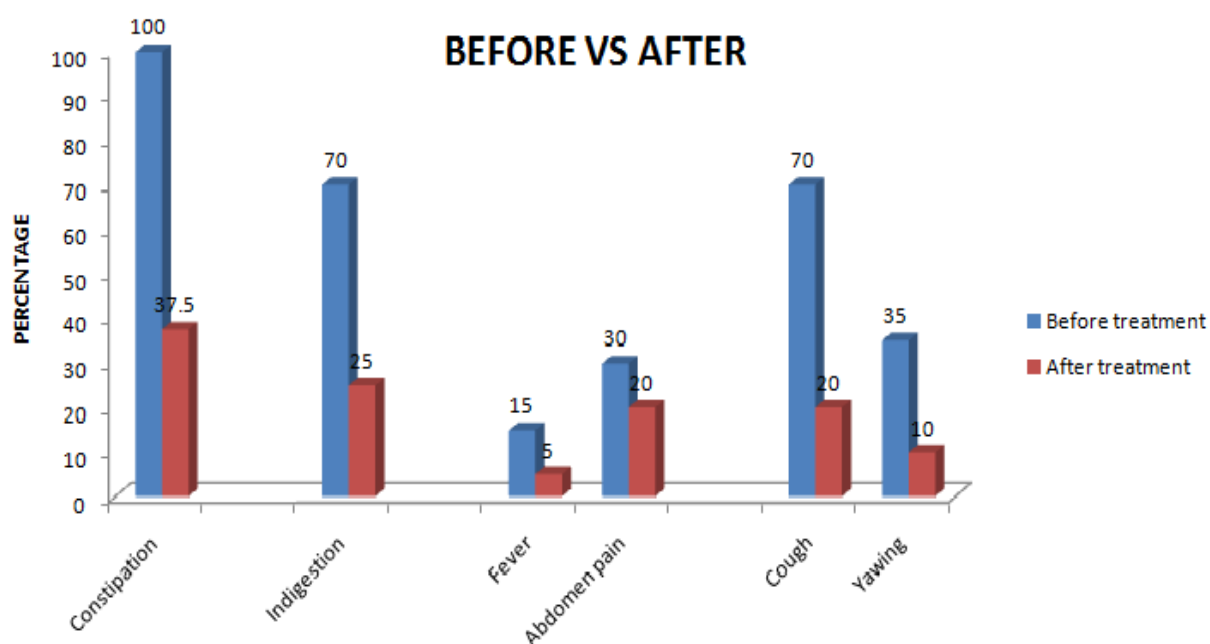
### **Inference**

Among the 40 cases, 100% of the patients have constipation, 75% have abdomen pain, 70% have Indigestion, 15% have fever, 70% have cough and 35% have yawning

**Table – 16 Results.**

**Table11. Distribution of patients with Kattu mantham according treatment results obtained**

Clinical Features	Before Treatment	Percentage (%)	After treatment	Percentage (%)
Constipation	40	100	15	37.5
Indigestion	28	70	10	25
Fever	6	15	2	5
Abdomen pain	75	30	8	20
Cough	28	70	8	20
Yawning	14	35	4	10



**Inference:**

Out of the 40 cases, the signs and symptoms like constipation 100 %, indigestion 70%, fever 15%, abdominal pain 30%, cough 70%, yawning 35% were reduced into 37.5%, 25%, 5%, 20%, 20%, 10% reduced respectively . These results were based on the clinical improvements observed.

## For clinical studies

### Statistical analysis:

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. Bar diagram, Pie charts were used to describe the value of different variables for pictorial representation. The quantity variables were expressed as Mean and standard deviation and qualitative data as percentage. A probability value of less than 0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

### Clinical Symptoms score before and after treatment

Treatment	Mean $\pm$ Std Dev	95% of C.I	Significance (t, p)
Before (40)	0.533	4.479	t-value=23.9075 p<0.001
After (40)	0.952	1.320	

The mean and standard deviation of Before and After treatment were 0.533 and 0.952 respectively. Which is statistically significant t-value =23.9075 p value p<0.0001

The reduction of clinical symptoms after the treatment is significant. The reduction in the symptoms is 65 % from the start of the treatment.

## 7. DISCUSSION

Kattumantham is a Functional Dyspepsia . It is defined as persistent or recurrent pain or discomfort centered in the abdomen , without evidence of organic disease. Functional dyspepsia is the most commonest health problem encountered in primary care worldwide, present about 80% of paediatric population.

### Preclinical studies

- **Biochemical analysis**

The Bio chemical analysis of trial medicines showed presence of calcium, magnesium ,aluminium ,sulphate ,zinc, alkaloids phenol, hydro quinine and tannic acid

Presence of tannic acid – drug containing tannins possess anti ulcer activity ,it reduce symptoms of dyspepsia

Presence of calcium – calcium ions significantly increase the drug release .it enhance the drug to absorb well.

### Physicochemical analysis:

physic-chemical analysis was done as preliminary evaluation of Seenthil kudineer .The method of measuring the moisture content in solid or semi-solid materials is loss on drying at 105 C<sup>0</sup> was found to be it falls in between the limit range(1-20%) The method of measuring the moisture content in solid materials is loss on drying (LOD) .Low moisture content is always desirable for higher stability of drugs. In Seenthil kudineer showed Loss of drying at 105C<sup>0</sup> was found to be 10.27 % it falls in between the limit range( 1-20%).so the moisture content shows the good stability of the drug Seenthil kudineer

The ash value represents the purity of the drugs.The total ash includes both physiological ash, which is derived from the organic matter, and non physiological ash which is the residue of the extraneous matters like sand/soil, inorganic materials. The non physiologic ash is represented by acid soluble ash .The total ash in Seenthil kudineer found to be 4.92% and the acid insoluble ash to be 0.53%. The both ash value were under limits. The minimal level of acid insoluble ash shows the less inorganic residue and purity of the Seenthil kudineer .

The extractive values helps to indicate the nature of chemical constituents present in the drug. The water soluble substance is polar in nature and the alcohol has the ability to dissolve non-polar substance .The water soluble extract value of Seenthil kudineer is 20.55%



and the Alcohol soluble extractive is 15.20 % its shows the possibility of water soluble constituents such as tannins, sugars, plant acids and mucilage, and alcohol soluble substance such as tannins, resins, and alkaloids to be present in the drug. As the drug Seenthil kudineer having more water soluble constituents than alcohol soluble, it would be non polar .So the trial drug shows good absorption & intracellular distribution without possible of accumulation inside the cells. The good water solubility may rapid the drug absorption and action.

Strongly acidic nature of the drug can cause the harmful effects to the body .so the screening for the pH is important for the drug .It represents the chemical nature of the drug and the site of absorption of non polar drug. The pH of Seenthil kudineer is found to be 4.70 that is weakly acidic and safe in pH. The weakly acidic drugs are rapidly absorbed from stomach. So the trial drug Seenthil kudineer can act rapidly on oral administration.

#### **In vitro carminative activity of Seenthil kudineer**

In-vitro carminative activity of the SeenthilKudineer was evaluated by modified method of Swapnil Sharma et al clearly indicates the test drug Seenthil kudineer (SK) The carminative profiling of the test sample SeenthilKudineer was evaluated on basis of the amount of cabondioxide evolved from the reaction mixture with varying volume of SK. The maximum amount of cabondioxide {g} produced by the 20ml of the sample SKwas found to be ( $12.53 \pm 0.53$ ) and 40 ml of sample it was ( $16.17 \pm 0.75$ ) .

#### **CLINICAL REVIEW**

- **Age:**

In the present study, Out of 40 patients, 62.5% of cases were within 1-2 years, 37% were within 2-3 years.

- **Sex:**

Out of 40 patients 62.5% patients were male children and 37.5 % patients were female children. Male children affected more than female children.

- **Socio-economic status:**

About 7.5% patients were under lower income group, 80% patients were under middle income group and 12.5% patients were under high income group. The highest incidence occurred in middle income group.

- **Seasonal variation:**

According to Paruvakalam high incidence of cases 65% were reported in pin pani kaalam and 2.5% were reported in elavenil kaalam and 27.5% were reported in Munpani kaalam 2.5% in kar kalam and 2.5% in koothir kalam .

- **Food habits:**

According to food habits 7.5% had vegetarian diet 92.5% had mixed diet The highest incidence of cases was observed in mixed diet

- **Nilam:**

Among 40 patients, 95% were from Neithal land, 5% from Marutham land.

- **Vali (Vatham)**

Due to the derangement of vatha the following symptoms occur. Abanan was affected in 100 % of cases and cause constipation . Viyanan was affected in 100% of cases. Samanan was affected in 100% cases and cause poor appetite. Uthanan was affected in 70% of cases and cause cough , Kirukaran was affected in 100% and cause cough and Poor appetite and devathathan was affected in 100% and cause general body weakness.

- **Azhal (Pitham)**

Due to the derangement of Pitham the following symptoms occur. Analapitham was affected in 100% of cases and cause poor appetite and ranjagam was affected in 10 % of cases and cause anemia .

- **Iyyam (Kabam)**

Deranged avalbagam was in 100% of cases, Klethagam was affected 100 % of cases cause poor appetite .

- **Ezhu udarkattugal**

In Ezhu udal kattukal, Saram was affected 100% and due to Cough, Poor appetite. Senneer was affected in 10% of cases due to anemia.

- **Envagai thervugal**

According to this study

Malam was affected in 100% of cases.

niram was affected in 10% of cases

Vizhi was affected 10% of cases

Moothiram was affected 10% of cases

Sparisam was affected in 15% of cases (Low grade fever)

- **Naadi:**

Vathapitham was observed in 50 % of cases

Pithavatham was observed in 50% of cases

According to naadi, high Distribution observed in vali Azhal, Azhal vali naadi. In siddha literature, the character of vali Azhal is due to poor appetite, indigestion and nausea.

- **Neerkuri**

Regarding moothiram, neerkuri showed straw coloured urine in all cases.

- **Neikuri**

In the present study, 50% of patient had vatha neikuri, 42.5% was observed as pitta neikuri and 7.5 % was observed as Kaba neikuri .According to this neikuri, vatham was dominately affected.

### **Clinical features:**

The clinical feature of kattumantham may be correlate with general clinical manifestations of Dyspepsia In accordance with the clinical features of *kattumantham* Among the 40 cases, 100% of the patients have constipation , 75% have abdomen pain, 70% have Indigestion and 70 % have cough, 15% have fever and 35% have yawning

### **Improvement in clinical features:**

Regarding the symptoms,. Out of the 40 cases, the signs and symptoms like constipation 100 % , indigestion 70%, fever 15%, abdominalpain 30% ,cough 70%, yawing 35% were reduced into 37.5% ,25% ,5%, 20% ,20%, 10% reduced respectivltly . These results were based on the clinical improvements observed

The mean and standard deviation of Seenthil kudineer before and after treatment were 0.533 and 0.952 respectively .Which is statistically significant t-value =23.9075 p value  $p < 0.0001$

The reduction of clinical symptoms after the treatment is significant. The reduction in the symptoms is 65 % from the start of the treatment.

## 8. SUMMARY

- ❖ The disease Kattu mantham was taken for the clinical study with Seenthil kudineer after scrutinizing by the Screening committee of National Institute of Siddha.
- ❖ The Clinical studies were carried out after obtaining proper permission from approval IEC of National Institute of Siddha (No:NIS/IEC/18-14/18-26-08-2014).
- ❖ The trial registred in Clinical trial Registry of India with Reg .No.CTRI/2016/04/006818 was obtained.
- ❖ The Authentication of ingredients of the trial drug was done obtained from Medicinal Botanist, National Institute of Siddha, Chennai.
- ❖ Purification of raw drugs and preparation of trial drug was done at Gunapadam Laboratory, Department of Gunapadam, NIS Chennai.
- ❖ Biochemical Qualitative analysis of trial drug was done in Biochemistry laboratory, Department of Biochemistry, National Institute of Siddha, Chennai.
- ❖ Physicochemical analysis of Seenthil kudineer was done in CRI Arumbakkam,Chennai
- ❖ In- vitro carminative Activity of trial drug was done in Satya Bama University,Chennai
- ❖ All the 40 patients, were treated in OPD of Kuzhandhai Maruthuvam department at Ayothidoss Pandithar Hospital of National Institute of Siddha.
- ❖ The patients with Kattu mantham were recruited based on Inclusion and Exclusion criteria and a detailed study was done. Separate proforma was maintained for each patient along with progress chart to monitor the prognosis.
- ❖ The mean and standard deviation of Seenthil kudineer before and after treatment were 0.533 and 0.952 respectively .Which is statistically significant t-value =23.9075 p value  $p<0.0001$
- ❖ The result shows 65% reduction in the clinical symptoms of patients after treatment and thus proves the efficacy of the medicine
- ❖ The physicochemical analysis showed the trial drug is in appropriate consistency for trial study .
- ❖ The patients have not complained of any adverse effects or difficulties during the course of treatment. Thus the drug is found to be safe and effective in the management of Kattu mantham.
- ❖ The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria.The observation made during the clinical study showed that the trail drug *Seenthil kudineer* was clinically effective.

## 9.CONCLUSION

The Siddha system of medicines has certainty with safer medications to treat children.

The present study indicates the purity and stability of the Seenthil kudineer .The result of In –vitro Carminative Activity of Seenthil kudineer possess promising Carminative property.

The trial drug Seenthilkudineer is treated to the children of age group,1-3 years who are all diagnosed to have kattu mantham.The ingredients of Seenthilkudineer are feasible and these compounds may serve as potentially useful drug at lower cost since most of them had carminative, laxative activity which controls kattu mantham.

Clinical results were found to be significant. Good improvement was found in 65% of cases .

The present clinical study has established that Seenthilkudineer is having good result in reducing the majority of the symptoms of kattumantham..This has in turn provided a further research and opportunity for new drug established in the management of Kattu Mantham. Because of the encouraging result of above study, the drug Seenthil kudineer may be taken for larger study in treatment of Kattumantham.

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- Kannusamy parambarai vaithiyam

### Web Sites

- <http://emedicine.medscape.com/article/1294744-overview>
- [http://www.ijpbs.net/cms/php/upload/2108\\_pdf.pdf](http://www.ijpbs.net/cms/php/upload/2108_pdf.pdf)
- <http://saspublisher.com/wp-content/uploads/2014/03/SAJB-22132-136.pdf>
- <http://www.ncbi.nlm.nih.gov/books/NBK92765>
- <http://www.journalcra.com/article/areca-catechu-comprehensive-pharmacological>  
<http://imsear.li.mahidol.ac.th/handle/123456789/144976>
- International Journal Of Science And Research (Ijsr)
- Issn (Online): 2319-7064impact Factor (2012): 3.358volume 3 Issue 7, July 2014

**ANNEXURES**  
**NATIONAL INSTITUTE OF SIDDHA,**  
**AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.**

**DEPARTMENT OF KUZHANDHAI MARUTHUVAM**

**CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHA DRUG IN THE  
TREATMENT OF KATTUMANTHAM (DYSPEPSIA) IN CHILDREN.**

**SCREENING FORM -I**

1. S.L No:	2. OP/ IP No:	3.Name:
4. Age:	5.Gender:	6.Date of Enrollment:
7. Date of completion:	8.Informant:	9.Reliability:

**INCLUSION CRETERIA:**

	YES	NO
Age: between 1 - 3 years	<input type="checkbox"/>	<input type="checkbox"/>
Constipation	<input type="checkbox"/>	<input type="checkbox"/>
Indigestion	<input type="checkbox"/>	<input type="checkbox"/>
Abdomen pain	<input type="checkbox"/>	<input type="checkbox"/>
Fever(below 102°F)	<input type="checkbox"/>	<input type="checkbox"/>
Cough	<input type="checkbox"/>	<input type="checkbox"/>
Yawning	<input type="checkbox"/>	<input type="checkbox"/>

**EXCLUSION CRITERIA**

High temp > 102F	<input type="checkbox"/>	<input type="checkbox"/>
Botulism	<input type="checkbox"/>	<input type="checkbox"/>
Hirsch sprung disease	<input type="checkbox"/>	<input type="checkbox"/>
Irritable bowel syndrome	<input type="checkbox"/>	<input type="checkbox"/>
Severe vomiting	<input type="checkbox"/>	<input type="checkbox"/>

**ADMITTED IN STUDY**

**If YES**

**OPD**

**IPD**

☐
☐

**SL NO OF THE PATIENT**

O\_\_\_\_

I\_\_\_\_

Signature of Lecturer:

Signature of HOD:

Signature of Principal Investigator:



**NATIONAL INSTITUTE OF SIDDHA**  
**AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.**  

<b>DEPARTMENT OF KUZHANDHAI MARUTHUVAM</b>
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**A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU  
MANTHAM IN CHILDREN**

**CONSENT FORM –II**

**CERTIFICATE BY INVESTIGATOR**

I certify that I have disclosed all the details about the study in the terms readily understood by the parent/guardian

Signature \_\_\_\_\_

Date \_\_\_\_\_

Name \_\_\_\_\_

**CONSENT BY PARENT**

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my son/daughter body functions.

I am aware of my right to opd my son/daughter out of the trail at any time during the course of the trail without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of '**seenthil kudineer**' for the treatment of kattu mantham

Date : \_\_\_\_\_ Signature \_\_\_\_\_

Name \_\_\_\_\_

Date : \_\_\_\_\_ Signature of witness Name \_\_\_\_\_

தேசிய சித்த மருத்துவ நிறுவனம்  
அயோத்திதாச பண்டிதர் மருத்துவமனை சென்னை-47  
குழந்தை மருத்துவத்துறை

சீந்தில் குடிநீர் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு  
ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த மருத்துவ ஆய்வை குறித்த அனைத்து விபரங்களையும்  
நோயாளியின் பெற்றோருக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதி  
அளிக்கிறேன்.

தேதி:

கையொப்பம்:

இடம்:

பெயர்:

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும்  
மருத்துவ வழிமுறைப் பற்றியும், இந்த மருத்துவத்தை தொடர்ந்து எனது குழந்தையின்  
உடல் இயக்கத்தைக் கண்காணிப்பது பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு  
மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்போது  
வேண்டுமானாலும் என் குழந்தையை விடுவித்துக் கொள்ளும் உரிமையை  
தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு கட்டு  
மாந்த நோய்க்கான சீந்தில் குடிநீர் பரிகரிப்புத் திறனை கண்டறியும் மருத்துவ  
ஆய்வுக்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:

பெற்றோர் பெயர்

இடம்:

கையொப்பம்:

சாட்சிக்காரர் பெயர்

கையொப்பம்

உறவு முறை:

**NATIONAL INSTITUTE OF SIDDHA**  
**AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.**  
**DEPARTMENT OF KUZHANDHAI MARUTHUVAM**

**A CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHA DRUG IN  
THE TREATMENT OF KATTU MANTHAM (DYSPEPSIA) IN CHILDREN**

**Form III- CASE REPORT FORM**

**1. HISTORY TAKING**

**Demographic data**

SL No :	OP/IP No.	Visit Date : (___/___/___)
Name :		
Age :		
Gender	Male <input type="checkbox"/> Female <input type="checkbox"/>	Date Of Birth : (___/___/___)
Father/ Mother /Guardian Name :		
Fathers Occupation :		
Fathers Monthly Income :		
Religion :		
Socioeconomic Status :		
Patient Informant :		

Postal Address

Contact No.

**1.COMPLAINTS AND DURATION:**

-----  
-----  
-----  
-----

**2. PRESENT ILLNESS :**

-----  
-----  
-----  
-----

**3. HISTORY OF PAST ILLNESS:**

-----  
-----  
-----

**4. FAMILY HISTORY:**

Any Hereditary/ Familial Disease    Yes ☐                      No ☐

If Yes, Details -----

**5. IMMUNIZATION HISTORY:**

Immunization                      complete ☐ Incomplete ☐    Complete but time lag ☐

**6. FOOD HABITS:**

1. Veg ☐                      2. Non-Veg ☐                      3. Mixed ☐

**7. GENERAL EXAMINATION:**

1. Pallor	YES <input type="checkbox"/>	NO <input type="checkbox"/>
2. Jaundice	YES <input type="checkbox"/>	NO <input type="checkbox"/>
3. Cyanosis	YES <input type="checkbox"/>	NO <input type="checkbox"/>
4. Clubbing	YES <input type="checkbox"/>	NO <input type="checkbox"/>
5. Pedal oedema	YES <input type="checkbox"/>	NO <input type="checkbox"/>
6. Lymph adenopathy	YES <input type="checkbox"/>	NO <input type="checkbox"/>

## **8. VITAL SIGNS :**

1. Pulse rate / min -
2. Heart rate / min -
3. Respiratory Rate / min -
4. Temperature -

## **ANTHROPOMETRY:-**

Height -

Weight -

## **CLINICAL EXAMINATION:**

### **ALIMENTARY SYSTEM**

#### **A )INSPECTION:**

Shape of the Abdomen : Distended / Scaphoid  
Scars : Present / Absent  
Umbilicus : Inverted / Everted  
Visible veins : Present / Absent  
Peristaltic waves : Present / Absent

#### **b) PALPATION:**

Tenderness : Present / Absent  
Palpable mass : Present / Absent  
Enlargement : Present / Absent

#### **c) PERCUSSION:**

Shifting dullness : Present / Absent  
Fluid Thrill : Present / Absent

#### **d) AUSCULTATION:**

Bowel sounds : Absent/ Normal / Increased / decreased\_\_\_\_\_

**Other systems:**

Cardio vascular system : Normal ☐ Affected ☐

Gastro intestinal system : Normal ☐ Affected ☐

Musculo skeletal system : Normal ☐ Affected ☐

Central nervous system : Normal ☐ Affected ☐

Endocrine system : Normal ☐ Affected ☐

**SIDDHA ASSESSMENT****Nilam:-**

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

**Kaala Iyalbu:-**

Kaarkalam ☐ Koothirkaalam ☐ Munpanikaalam ☐

Pinpanikaalam ☐ Illavenirkaalam ☐ Muthuvenirkaalam ☐

**Yaakai:-**

Vatham ☐ Vatha Pitham ☐ Vatha Kabam ☐

Pitham ☐ Pitha vatham ☐ Pitha Kabam ☐

Kabam ☐ Kaba Vatham ☐ Kaba Pitham ☐

**Gunam**

Sathuvam ☐ Rasatham ☐ Thamasam ☐

**Pori / Pulangal**

	Normal	Affected	Remarks	Normal	Affected	Remarks
Mei / unarvu	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Vaai / suvai	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Kan / parvai	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	

Mooku / natram	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sevi / olli	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Kanmendhirium / Kanmavidayam

	Normal	Affected	Remarks	Normal	Affected
Kai / dhanam	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Kaal / ghamanam	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Vaai / vaaku	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Eruvai / visarkam	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Karuvai / anantham	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

### Uyir Thathukkal

<b>Vatham:</b>	Normal	Affected	Remarks
Pranan	<input type="checkbox"/>	<input type="checkbox"/>	
Abanan	<input type="checkbox"/>	<input type="checkbox"/>	
Viyanan	<input type="checkbox"/>	<input type="checkbox"/>	
Uthanan	<input type="checkbox"/>	<input type="checkbox"/>	
Samanan	<input type="checkbox"/>	<input type="checkbox"/>	
Nagan	<input type="checkbox"/>	<input type="checkbox"/>	
Koorman	<input type="checkbox"/>	<input type="checkbox"/>	
Kirukaran	<input type="checkbox"/>	<input type="checkbox"/>	
Devathathan	<input type="checkbox"/>	<input type="checkbox"/>	
Dhanajeyan	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Pitham:</b>	Normal	Affected	Remarks
Analam	<input type="checkbox"/>	<input type="checkbox"/>	
Ranjagam	<input type="checkbox"/>	<input type="checkbox"/>	
Saathagam	<input type="checkbox"/>	<input type="checkbox"/>	
Alosagam	<input type="checkbox"/>	<input type="checkbox"/>	
Prasagam	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Kabam :</b>	Normal	Affected	Remarks
Avalambagam	<input type="checkbox"/>	<input type="checkbox"/>	
Kilethagam	<input type="checkbox"/>	<input type="checkbox"/>	
Pothagam	<input type="checkbox"/>	<input type="checkbox"/>	
Tharpagam	<input type="checkbox"/>	<input type="checkbox"/>	
Santhigam	<input type="checkbox"/>	<input type="checkbox"/>	

### **Udalthathukkal**

	Normal	Affected	Remarks
Saaram	<input type="checkbox"/>	<input type="checkbox"/>	
Senneer	<input type="checkbox"/>	<input type="checkbox"/>	
Oon	<input type="checkbox"/>	<input type="checkbox"/>	
Kozhuppu	<input type="checkbox"/>	<input type="checkbox"/>	
Enbu	<input type="checkbox"/>	<input type="checkbox"/>	
Moolai	<input type="checkbox"/>	<input type="checkbox"/>	
Sukilam / Suronitham	<input type="checkbox"/>	<input type="checkbox"/>	

### **Envagai Thervugal**

	Normal	Affected	Remarks
<b>Naa</b>			
Niram	<input type="checkbox"/>	<input type="checkbox"/>	
Thanmai	<input type="checkbox"/>	<input type="checkbox"/>	
Suvai	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Niram</b>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Mozhi</b>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Vizhi</b>			
Niram	<input type="checkbox"/>	<input type="checkbox"/>	
Thanmai	<input type="checkbox"/>	<input type="checkbox"/>	
Paarvai	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Sparisam</b>	<input type="checkbox"/>	<input type="checkbox"/>	



**Malam**

Niram                      Normal ☐ Affected ☐

Nurai                      Normal ☐ Affected ☐

Elagal                      Normal ☐ Affected ☐

Erugal                      Normal ☐ Affected ☐

**Moothiram**

**Neerkuri:**    Niram                      Normal ☐ Affected ☐

Edai                      Normal ☐ Affected ☐

Nurai                      Normal ☐ Affected ☐

Manam                      Normal ☐ Affected ☐

Enjal                      Normal ☐ Affected ☐

**Neikuri:**

Vatham                      ☐

Pitham                      ☐

Kabam                      ☐

Others                      ☐

**Naadi:**

Date : \_\_\_\_\_

Station : \_\_\_\_\_

Signature of the Investigator:

Signature of the Lecturer:

Signature of the HOD:

## DEPARTMENT OF KUZHANDHAI MARUTHUVAM

# CLINICAL EVALUATION OF SEENTHIL KUDINEER A SIDDHA DRUG IN THE TREATMENT OF KATTUMANTHAM (DYSPEPSIA) IN CHILDREN.

1. S.I. No:	2. OP/ IP No:	3.Name:
4. Age:	5.Gender:	6.Date of Enrollment:
7. Date of completion:	8.Informant:	9.Reliability

SL.NO.	Clinical Features	1 <sup>ST</sup> DAY	2 <sup>ND</sup> DAY	3 <sup>RD</sup> DAY
1	Constipation			
2	Consistency			
3	Abdominal Pain			
4	Fever			
5	Indigestion			
6	Cough			
7	Yawning			

Investigator:

Signature of the Lecturer:  
Signature of the HOD:



## FORM VI PATIENT INFORMATION SHEET

**Name of Principal Investigator** : \_\_\_\_\_  
**Name of the institute** : National Institute of Siddha,  
Tambaram Sanatorium,  
Chennai-47.

### INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, \_\_\_\_\_ Studying as PG Scholar at National Institute of Siddha, Tambaram Sanatorium is doing a trial on the study “KATTU MANTHAM”. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree your child to be a participant in this study, he/she will be included in the study primarily by signing the consent form and then you will be given the internal medicine SEENTHIL KUDINEER[10ml-twice a day].

The information I am collecting in this study will remain between you and the principal investigator (myself).

If you wish to find out more about this study before taking part, you can contact myself Dr.P.MIRUNALENI, PG Scholar 8122978302. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel no : 91-44-22380789, for rights and participation in the study.

## தகவல் படிவம்

கட்டு மாந்தம் நோய்க்கான சித்த மருந்தின் (சீந்தில் குடிநீர் ) பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் : ப. மிருணாளினி  
நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்  
தாம்பரம் சனட்டோரியம் சென்னை-47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் கட்டு மாந்தம் என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

கட்டு மாந்தம் என்னும் சித்த மருத்துவத்தில் சொல்லப்படும் நோயானது இருமல், மலக்கட்டு, சுரம், வயிற்று வலி, பசி இன்மை, முதலிய குறிகுணங்கள் காணப்படும் தன்மையுடையது.

இது சம்மந்தமான தங்களது குழந்தையின் அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன். இதில் பயணப்படி முதலிய எந்த உதவி தொகையும் வழங்கப்பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது தங்களது குழந்தையின் உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க சிசிச்சை அளிக்கப்படும்.

இந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் குழந்தையை உட்படுத்தும் பட்சத்தில் உள்மருந்தாக சீந்தில் குடிநீர் [10 மிலி] 1 நாள் எடுக்க வேண்டும்.

இந்த ஆராய்ச்சியில் நோயினராக சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் தங்களது குழந்தையை விலக்கிக் கொள்ளலாம்.

இந்த ஆராய்ச்சி சம்மந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் அறிவதற்கும் முதன்மை ஆராய்ச்சியாளர் (பட்ட மேற்படிப்பாளர் குழந்தை மருத்துவ பிரிவு) கைபேசி எண் 8122978302 எப்போதும் தொடர்பு கொள்ளலாம்.

மேலும் இந்த ஆராய்ச்சிக்கு IEC (நிறுவன நீதிநெறிகுழு) சான்று பெறப்பட்டுள்ளது.

இந்த மருத்து சிறப்பாக கட்டு மாந்தம் நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது. ஏற்கனவே உபயோகத்தில் உள்ளது . இதுவரை நோயாளிகளிடம் எந்த வித பக்க விளைவுகளை ஏற்படுத்தவில்லை.

**NATIONAL INSTITUTE OF SIDDHA**  
**AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.**

**DEPARTMENT OF KUZHANDHAI MARUTHUVAM**

**A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR  
KATTU MANTHAM IN CHILDREN.**

**FORM VII WITHDRAWL FORM**

1. S.I. No:	2. OP/ IP No :	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Date of completion:	8. Informant:	9. Reliability:

---

Date of trial commencement	:
Date of withdrawal from trial	:
Reason(s) for withdrawal	: Yes/ No
Long absence at reporting	: Yes/ No
Irregular treatment	: Yes/ No
Shift of locality	: Yes/ No
Complication adverse reactions if any	: Yes/ No
Exacerbation of symptoms	: Yes/ No
Patient not willing to continue	: Yes/ No

Date:

Signature of Principal Investigator

**NATIONAL INSTITUTE OF SIDDHA**  
**AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.**

**DEPARTMENT OF KUZHANDHAI MARUTHUVAM**

**A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU  
MANTHAM IN CHILDREN.**

**FORM VIII-ADVERSE REACTION**

1. S.I. No:	2. OP/ IP No :	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Date of completion:	8. Informant:	9. Reliability:

---

Name	:
Age	:
Gender	:
OPD/ IPD No	:
Registration No	:
Date of trial commencement	:
Date of withdrawal from trial	:
Description of adverse reaction	:

Date:

Signature of Principal Investigator

**1. Patient / consumer identification (please complete or tick boxes below as appropriate)**

**NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS**

**Reporting Form for Suspected Adverse Reactions to Siddha Drugs**

**Please note:** i. All consumers / patients and reporters information will remain confidential.  
ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code:

State:

Name	Father name	Patient / Record No.
Ethnicity	Occupation	
Address		Date of Birth / Age:
Village / Town		Sex: Male / Female Weight : Degam:
Post / Via		
District / State		

**2. Description of the suspected Adverse Reactions (please complete boxes below)**

Date and time of initial observation		Season:
Description of reaction		Geographical area:



**3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:**

Medicine	Daily dose	Route of administration & Vehicle – Adjuvant	Date		Diagnosis for which medicine taken
			Starting	Stopped	
Siddha					
Any other system of medicines					

**4. Brief details of the Siddha Medicine which seems to be toxic :**

Details	Drug – 1	Drug – 2	Drug - 3
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			
c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

**5. Treatment provided for adverse reaction:**

**6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)**

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:			
	Reaction reappeared after re introduction:			

Was the patient admitted to hospital? If yes, give name and address of hospital	
---	--

**7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:**

**8. Whether the patient is suffering with any chronic disorders?**

Hepatic          Renal          Cardiac          Diabetes          Malnutrition

Any Others

**9. H/O previous allergies / Drug reactions:**

**10. Other illness (please describe):**

**11. Identification of the reporter:**

<b>Type</b> (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer /  Distributor / Supplier / Any others (please specify)
<b>Name:</b>
<b>Address:</b>
<b>Telephone / E – mail if any :</b>

**Signature of the reporter:**

**Date:**

**Please send the completed form to:**

Name & address of the RRC- ASU / PPC-ASU
---

The Director  
National Institute of Siddha,  
(Pharmacovigilance Regional Centre For Siddha dicine),  
Tambaram Sanatorium, Chennai-600 047.  
☎ (O) 044-22381314      Fax : 044 – 22381314  
Website : [www.nischennai.org](http://www.nischennai.org)  
Email: [nischennaisiddha@yahoo.co.in](mailto:nischennaisiddha@yahoo.co.in)

\*\*\*\*\*

**This filled-in ADR report may be sent within one month of observation /occurrence of ADR**

**Who Can Report?**

⇒ Any Health care professionals like Siddha Doctors / Nurses / Siddha Pharmacists / Patients etc.

**What to Report?**

⇒ All reactions, Drug interactions,

**Confidentiality**

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent.

⇒ Submission of report will be taken up for remedial measures only not for legal claim

**NATIONAL INSTITUTE OF SIDDHA  
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.**

**DEPARTMENT OF KUZHANDHAI MARUTHUVAM**

**A CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU  
MANTHAM IN CHILDREN**

**FORM IX-DIETARY ADVICE FORM**

<b>✓ THINGS TO TAKE</b>	<b>✗ THINGS TO AVOID</b>
Fruits-Fig,Papaya,Gauva,Grapes,Bananas, apples, orange,dates	Refridged items
All greens eg-palak	Tin and canned foods
Fresh vegetable soups	Cream containing biscuits and cakes
Boiled water	Junk and fast foods
Fiber rich foods eg-whole-grain breads and cereals,almonds,legumes  Use palm candy instead of white sugar	White sugar



## NATIONAL INSTITUTE OF SIDDHA

राष्ट्रीय सिद्ध संस्थान

Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE

आयुष विभाग - स्वास्थ्य एवं परिवार कल्याण मंत्रालय

GOVERNMENT OF INDIA-भारत सरकार

TAMBARAM SANATORIUM, CHENNAI -600 047 -तामवरम सनटोरियम चेन्नई -600 047

फोन/Tele : 044-22411611

फैक्स/Fax : 22381314

ईमेल: [nischennaisiddha@yahoo.co.in](mailto:nischennaisiddha@yahoo.co.in)

वेब: [www.nischennai.org](http://www.nischennai.org)

F.No.NIS/6-20/IEC/14-15

Dt: 25.09.14

### CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.P.Mirunaleni, P.G.Student, Kuzhandhai Maruthuvam	
Protocol title: A clinical evaluation of Seenthil kudineer a Siddha drug for Kattumantham (Dyspepsia) in children	
Documents filed	1) Protocol, 2) Data Collection forms 3) Patient Information Sheet 4) Consent form 5) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	NIS/IEC/8-14/20 - 26-08-2014

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent.

  
Chairman

  
Member Secretary



**NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047**

**CERTIFICATE OF BOTANICAL AUTHENTICITY**

Certified that the following plant drugs used in the Siddha formulation “**Seenthil kudineer**” (Internal) for the treatment of **Kattumantham** (Dyspepsia) taken up for Post Graduation Dissertation studies by **Dr.P.Mirunaleni**, M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2015, are identified and authenticated through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology, Micromorphology and Taxonomical methods as

***Tinospora cordifolia*** (Willd.) Meirs (Menispermaceae), Stem

***Areca catechu*** Linn. (Arecaceae), Nut

***Operculina turpethum*** (Linn.) Silova Manso (Convolvulaceae), Root

***Terminalia chebula*** Retz. (Combretaceae), Fruit

***Zingiber officinale*** Rosc. (Zingiberaceae), Rhizome

***Picrorhiza kurroa*** Royle ex Benth. (Scrophulariaceae), Root

***Aloe barbadensis*** Mill. (Liliaceae), Dried leaf

Certificate No: NISMB1892015

Date: 27-08-2015

  
27/8/15  
Authorized Signatory

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், அரும்பாக்கம், சென்னை - 600106  
सिद्ध केन्द्रीय अनुसंधान संस्थान, अरुम्बाक्कम, चेन्नै - 600106

### Siddha Central Research Institute

(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)  
Arumbakkam, Chennai – 600106


[Ph: 044-26214925, 26214809, Fax: 26214809, Email: crisiddha@gmail.com, Web: www.siddhacouncil.com]

01.03.2016

Name of the student: Dr. P. Mirunaleni, II Year Kuzhandai Maruthuvam,  
National Institute of Siddha, Chennai-47.

#### PHYSICO-CHEMICAL ANALYSIS OF SEENTHIL KUDINEER

S.No	Parameter	Mean
1.	Loss on Drying at 105°C	: 10.27 %
2.	Total Ash	: 4.92 %
3.	Acid insoluble Ash	: 0.53 %
4.	Water Soluble Extractive	: 20.55 %
5.	Alcohol Soluble Extractive	: 15.20 %
6.	pH	: 4.70



(R. Shakila)  
Research Officer (Chemistry)

  
1/3/16

(Dr. P. Sathiyarajeshwaran)  
Assistant Director (Scientist 2) I/c



**FULL DETAILS (Read-only) -> [Click Here to Create PDF for Current Dataset of Trial](#)**

<b>CTRI No</b>	<b>CTRI/2016/04/006818</b> [Registered on: 12/04/2016] <b>Trial Registered Retrospectively</b>															
<b>Acknowledgement Number</b>	REF/2015/08/009557															
<b>Last Modified On:</b>	13/06/2016															
<b>Post Graduate Thesis</b>	Yes															
<b>Type of Trial</b>	Interventional															
<b>Type of Study</b>	Siddha															
<b>Study Design</b>	Single Arm Trial															
<b>Public Title of Study</b>	Clinical trail for dyspepsia in children															
<b>Scientific Title of Study</b> <a href="#">Clarification(s) with Reply Modification(s)</a>	CLINICAL EVALUATION OF SEENTHIL KUDINEER FOR KATTU MANTHAM (DYSPEPSIA) IN CHILDREN.															
<b>Acronym</b>																
<b>Secondary IDs if Any</b>	<table border="1"> <thead> <tr> <th>Secondary ID</th><th>Identifier</th></tr> </thead> <tbody> <tr> <td>NIL</td><td>NIL</td></tr> </tbody> </table>	Secondary ID	Identifier	NIL	NIL											
Secondary ID	Identifier															
NIL	NIL															
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b> <a href="#">Clarification(s) with Reply Modification(s)</a>	<table border="1"> <tr> <td><b>Name</b></td><td>Dr PMirunaleni</td></tr> <tr> <td><b>Designation</b></td><td>PG Scholar</td></tr> <tr> <td><b>Affiliation</b></td><td>National Institute of Siddha</td></tr> <tr> <td><b>Address</b></td><td>National Institute of Siddha Tambaram sanatorium Chennai-47 National Institute of Siddha Tambaram sanatorium Chennai-47 Chennai TAMIL NADU 600047 India</td></tr> <tr> <td><b>Phone</b></td><td>8122978302</td></tr> <tr> <td><b>Fax</b></td><td></td></tr> <tr> <td><b>Email</b></td><td>mirunalenibsms@gmail.com</td></tr> </table>		<b>Name</b>	Dr PMirunaleni	<b>Designation</b>	PG Scholar	<b>Affiliation</b>	National Institute of Siddha	<b>Address</b>	National Institute of Siddha Tambaram sanatorium Chennai-47 National Institute of Siddha Tambaram sanatorium Chennai-47 Chennai TAMIL NADU 600047 India	<b>Phone</b>	8122978302	<b>Fax</b>		<b>Email</b>	mirunalenibsms@gmail.com
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Modification(s)	<b>Address</b>		National Institute of Siddha Tambaram sanatorium Chennai-47 National Institute of Siddha Tambaram sanatorium Chennai-47 Chennai TAMIL NADU 600047 India	
	<b>Phone</b>		8122978302	
	<b>Fax</b>			
	<b>Email</b>		mirunalenibsms@gmail.com	
<b>Details Contact Person</b> <b>Public Query</b> Clarification(s) with Reply Modification(s)	<b>Name</b>		DrAAmalaHazel MDs	
	<b>Designation</b>		Lecturer	
	<b>Affiliation</b>			
	<b>Address</b>		National Institute of Siddha Tambaram sanatorium Chennai-47  Chennai TAMIL NADU 600047 India	
	<b>Phone</b>		9486909809	
	<b>Fax</b>			
	<b>Email</b>		dramalaarulldhas@gmail.com	
<b>Source of Monetary or Material Support</b>		Self		
<b>Primary Sponsor</b>	<b>Name</b>		National Institute of Siddha	
	<b>Address</b>		National Institute of Siddha Tambaram sanatorium Chennai-47	
	<b>Type of Sponsor</b>		Research institution and hospital	
<b>Details of Secondary Sponsor</b>	<b>Name</b>		<b>Address</b>	
	NIL		NIL	
<b>Countries of Recruitment</b>		India		
<b>Sites of Study</b> Clarification(s) with Reply Modification(s)	No of Sites = 1			
	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>

	Dr P Mirunaleni	Ayothidas s pandithar hospital	Room No -9 / Kuzhandhai maruthuva m Department ,Ayothidass pandithar hospital National Institute of Siddha Tambaram sanatorium Chennai Chennai TAMIL NADU	8122978302  mirunalenibsms@gmail.co m															
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Comparator Agent	Nil	Nil																	
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<b>Gender</b>	Both																		
<b>Details</b>	Indigestion Stomach Pain Cough Fever																		

	<div>Constipation</div>	
<b>Exclusion Criteria</b>	<b>Details</b>	Irritable Bowel syndrome Childhood asthma Intolerable stomach pain
<b>Method of Generating Random Sequence</b>		
<b>Method of Concealment</b>		
<b>Blinding/Masking</b>		
<b>Primary Outcome</b>	<b>Outcome</b>	<b>TimePoints</b>
	Relief from the symptoms	2 days
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>TimePoints</b>
	any toxicity of the drug	14 days
<b>Target Sample Size</b>	<b>Total Sample Size="40"</b> <b>Sample Size from India="40"</b>	
<b>Phase of Trial</b>	Phase 2	
<b>Date of First Enrollment (India)</b> <a href="#">Clarification(s) with Reply</a> <a href="#">Modification(s)</a>	15/09/2015	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years="1"</b> <b>Months="0"</b> <b>Days="0"</b>	
<b>Recruitment Status of Trial (Global)</b> <a href="#">Modification(s)</a>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment	
<b>Publication Details</b>	After the study	
<b>Brief Summary</b>	My trial drug contains Tinospora cardifolia (seenthil)	

	<p>thandu), Araca catechu (kali pakku), Operculina  terpethum (sivathai), Terminalia chebula (kadukkai), Zingiber  officinalis (sukku), Picrorhiza scrophulariiflora  (kadukurokini), Aloe barbadence (katralai sarugu). it is given to  children below 3 years orally twice a day in decotion form for  a day to releive constipation.</p>
--	---

## Ingredients of Seenthil Kudineer



Fig 1 *Zingiber officinalis*



Fig 2 *Picrorhiza scrophulariiflora*



Fig 3 *Araca catechu*



Fig 4 *Tinospora cardifolia*



Fig 5 - Terminalia chebula



Fig 6 - Aloe barbadence (katralai sarugu)



Fig 7 Operculina terpehthum



Fig 8 Seenthil kudineer